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Exhibit 674G

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Expert Column

Assessing Abuse Potential in Pain Patients

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Introduction

The prevalence of opiate abuse among patients with chronic pain is unknown but is believed to be no greater than the prevalence of opiate abuse in the general population.[1] Some studies disagree and estimate the danger of addiction or abuse for pain patients to be higher than the norm.[2,3] Other medical literature has put the prevalence of addictive disorders among patients who sustain major trauma as high as 60%.[4] Despite the common use of opioid analgesics in the treatment of chronic pain, considerable fear exists among physicians that prescribing opioid drugs may contribute to opiate abuse or addiction.

All physicians who prescribe opioid medications to chronic pain patients must assess patients for potential abuse. This can be done in 3 ways. The first way is to watch for aberrant behavior that may be associated with abuse or addiction. The second way is to be familiar with the individual risk factors for opiate abuse. The third way is by using assessment tools to evaluate, diagnose, and possibly predict abuse or addiction in patients.

Aberrant Behaviors

A number of aberrant behaviors (Table 1) are associated with drug abuse.[5,6] Although the display of any single behavior does not automatically indicate a problem with abuse or addiction, in the absence of a laboratory test to diagnose such disorders, the behavior displayed by the patient is the best indicator of potential abuse available to the clinician. This relationship to aberrant behaviors is reflected in the definitions of abuse and addiction found in the *Diagnostic and Statistical Manual of Mental Disorders*, *Fourth Edition*.[7]

Individual Risk Factors

Many individual risk factors are linked to aberrant behaviors that might indicate abuse or addiction. Clinicians need to monitor for these risk factors to minimize the risk of contributing to abuse or addiction. The following are what this author believes to be the most significant risk factors for developing opiate abuse in chronic pain patients.

Family History of Substance Abuse (Alcohol, Illegal Drugs, or Prescription Drugs)

A family history of substance abuse can create both genetic and environmental risk factors for developing substance abuse or addiction.[8,9] In a study of 3372 male twin pairs, Tsuang and colleagues[9] found that the risk of developing any drug use disorder is influenced about equally by genetic and environmental factors.

Personal History of Substance Abuse (Alcohol, Illegal Drugs, or Prescription Drugs)

Clinical observation reveals that when patients have a history of abusing prescriptions or illegal drugs, they are likely to continue the abuse and aberrant behavior. The higher the number of aberrant behaviors exhibited by the patient, the more likely they will display opiate abuse.

A retrospective study by Dunbar and Katz[10] showed that a recent history of polysubstance abuse was associated with aberrant behavior. One study[11] of personal polysubstance use has shown that most individuals hospitalized for alcohol treatment also abused one or more other substances in the 3 months before entering alcohol treatment.

According to Tsuang and associates,[12] an individual who developed a drug use disorder was 7 times more likely to

develop another drug use disorder.

Age

Onset of drug abuse can occur at very early ages. Middle-to-late adolescence into mid-20s appears to be when most drug experimentation occurs.[13-15]

A survey of 3500 respondents found that 22% of 18- to 30-year-olds had a substance abuse disorder.[14] Of those with multiple mental disorders, 80% reported the onset of a substance abuse disorder before the age of 20 years. Prevalence of nonalcohol substance abuse significantly declines later in life.[16]

History of Preadolescent Sexual Abuse

It is generally accepted that women who experienced preadolescent sexual abuse are at particular risk for mental and substance abuse disorders.[17-19] In a study of 286 women,[20] roughly 9% of the sample reported being victims of childhood sexual abuse, and of that group, 64% had been treated for depression for at least 3 years.

In another study,[21] investigators reported that 55% to 99% of women seeking substance abuse treatment who had a history of trauma had been sexually or physically abused by the age of 18 years.

One 10-year study[17] found that depression, anxiety, panic disorders, alcohol, and drug dependency all increased as a result of sexual abuse. Of all the disorders measured, drug dependency occurred most frequently following sexual abuse. There seems to be something uniquely traumatic to this experience that is associated with substance abuse later in life.

Psychological Diseases

Substance abuse has been associated with numerous psychological disorders.[14,22-26] Data indicate patients diagnosed as having attention-deficit/hyperactivity disorder, depression, anxiety, obsessive-compulsive disorder, schizophrenia, or bipolar disorder are at significant risk for abusing substances.[14,24,25]

One study[24] showed that among individuals with a lifetime mental disorder diagnosis, 22.3% displayed alcohol abuse or addiction and 14.7% exhibited drug abuse or addiction. Among those with no history of mental disorder, the rate of alcohol abuse was 11% and drug abuse was 3.7%. Thus, having a lifetime mental disorder is associated with more than twice the risk of experiencing an alcohol disorder and more than 4 times the risk of experiencing another drug abuse disorder.

Assessment Tools

Of the currently available diagnostic tools for opiate abuse, several take a long time to administer and require unique skills to interpret. Screening tools have 2 common problems when used to assess for potential opiate abuse in chronic pain patients. First, they are designed to identify patients who already have problems with substances not to predict who may develop problems, and second, they are not designed to screen specifically for opiate abuse.

Some, such as the CAGE (from "cut, annoyed, guilty, eye") and the Two-Item Conjoint Screening (TICS) tools have been adapted for use in opiate abuse screening but were originally designed as alcohol abuse screening tools. Others, such as the Structured Clinical Interview for *DSM-IV* (SCID) and Prescription Drug Use Questionnaire (PDUQ), have some predictive validity but are lengthy to administer and score.

One exception is the Webster Assessment Tool (manuscript in preparation). It screens new patients for the common risk factors discussed in this column and has been found to have high predictive validity.

The choice of which assessment tool to use will depend on the clinician's expertise or access to specialists in the field, the time available, and other aspects of the clinical situation. For new patients, predictive tools can help clinicians assess potential risk before treatment begins. For a current patient, when aberrant behavior is suspected, a diagnostic tool would be helpful.

Table 2 highlights the characteristics of the most common substance abuse assessment tools.

In conclusion, the purpose of assessing patients for the risk of abusing opiates is not to deny treatment to moderate-risk to high-risk patients. All patients deserve treatment for pain. However, higher-risk patients require more careful monitoring and clinical vigilance if opiates are to be safely prescribed. This should be done to mitigate the harm opiate abuse can

bring to society and to our patients. Clinicians can assess for potential opiate abuse by watching for aberrant behaviors, identifying individual risk factors and using specific validated assessment tools designed to detect opiate abuse. The method a clinician uses to assess for potential abuse must be tailored to the patient, taking into account the resources and expertise of the clinician.

Tables

Table 1. Aberrant Behaviors*[5]

Using more opiates than prescribed
Prescription forgery
Selling prescriptions
Seeking euphoria from opiates
Seeking relief from anxiety from opiates
Overdose and death
Injecting oral formulations
Abnormal urine or blood screen results
Soliciting opiates from other prescribers
Unauthorized emergency department visits
Concurrent abuse of alcohol
Unauthorized dose escalation
Resistance to therapy changes
Lost or stolen prescriptions
Clinic visit cancellation
Request for early refills
Request refills instead of clinic visit
Abuse of prescribed drug
Discharged from physician's practice
No show for follow-up
Third party required to manage patient's medications

*In no particular order of importance.

Table 2. Assessment Tools

Screener and Opioid Assessment for Patients With Pain (SOAPP)[31]	Yes/yes	Testing Ongoing	Self or interview	24 items, 10 minutes
Prescription Drug Use Questionnaire (PDUQ)[32]	No/yes	Yes	Interview	42 items, 20 minutes
RAFFT[33] (from "relax, alone, friends, family, trouble")	Yes/yes	No	Self	5 items, approximately 1 minute
Drug Abuse Screening Test (DAST)[34]	No/yes	No	Self	20 items, 5 minutes
Severity of Opiate Dependence Questionnaire (SODQ)[35]	No/yes	No	Self	21 items, approximately 5 minutes
Webster Assessment Tool (WAT)[5]	Yes/yes	Yes	Self	5 items, 1 minute

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REPORTS

Pain Clinicians' Rankings of Aberrant Drug-Taking Behaviors

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ABSTRACT. A pilot study was conducted to examine experienced pain physicians' perceptions of aberrant drug taking behaviors. One hundred

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pain physicians attending a meeting on pain management were asked to rank order (from most aberrant = 1 to least aberrant = 13) a list of aberrant drug-taking behaviors. The sample was comprised mainly of anesthesiologists (50%) and half of the group had 10 or more years of pain management experience. The group prescribed an average of 19-96 opioid medications per week. Practice variables were not related to the rank ordering of the behaviors. All of the various behaviors appeared in all 13 of the rank ordering slots, suggesting a great deal of individual difference in the perception of these behaviors. By examining the average ranking of the behaviors, we noted that physicians' focus on illegal behaviors as the most aberrant followed by the alteration of route of delivery and self-escalation of dose. This survey suggests that an experienced group of pain clinicians does not view aberrant drug related behaviors uniformly. Average rankings suggest clinicians seem to view illegal behavior as the most worrisome. These results must be interpreted with caution due to the small convenience sample, the lack of data on the level of addiction medicine training of the respondents and the lack of data on those physicians who chose not to respond. Further inquiry could be used to guide clinicians' responses to aberrant behaviors when encountered in patients on controlled substances for pain. *[Article copies available for a fee from The Haworth Document Delivery Service: 1-800-HAWORTH. E-mail address: <getinfo@haworthpressinc.com> Website: <http://www.HaworthPress.com>*

KEYWORDS. Pain, aberrant drug-taking behavior, addiction

INTRODUCTION

The use of chronic opioid therapy in the management of nonmalignant pain, that is, pain not derived from cancer-related factors, has been increasing in acceptability over the past decade.[1] The common observation that cancer patients benefit from these medications and do not encounter major abuse and diversion has led to the extending of this strategy to many other populations. Despite this growing acceptance however, chronic opioid therapy for nonmalignant pain remains controversial and thus requires meticulous attention to assessment and documentation of outcomes in four key domains.[2] These domains, which have been referred to as the "4As," include analgesia (pain relief), activities of daily living (psychosocial functioning), adverse effects (side effects) and aberrant drug-taking behaviors (addiction).

While it is helpful to have a tool and/or a vocabulary for noting aberrant behaviors as they might be occur in patients receiving chronic opioid therapy, the behaviors require clinical interpretation. There appears to be a difference

among behaviors along the continuum of aberrancy that has face validity, or the extent to which the behaviors simply appear to tap the construct it is supposed to measure. Some behaviors seem to be relatively common and not very aberrant, e.g., demanding more pain medication, occasional unilateral dose escalation. Others are illegal, uncommon and highly aberrant, e.g., prescription forgery. It appears that most clinicians concur about the high degree of aberrancy of these latter behaviors as well as others such as the intravenous injection of an oral formulation. Other behaviors are less blatant. However, when a drug is prescribed for a medically diagnosed purpose, less assuredness exists concerning the behaviors that could be considered aberrant and the potential for a diagnosis of drug abuse or addiction increases. Hence, none of these behaviors has a universal interpretation, and they must be viewed from the context of the multitude of influences that impact drug taking.[3-4]

The need for appropriate interpretation of patient behaviors is illustrated by the following case. Passik and Hay[5] published a case report on a young woman with borderline personality disorder, a psychiatric condition marked by impulsivity and an impoverished ability to relate to others in a non-dependent way, who forged a prescription for alprazolam to express her anger at her therapist who was away on vacation. This gesture was a typical (for this woman) way of expressing rage, fear of abandonment and self-defeating tendencies; as such it was a complex and psychologically meaningful act but had little to do with drug abuse or addiction. Thus, the clinician must attempt to "differentially diagnose" aberrant behavior by sorting out the potential influences so as to plan a clinical response. Among the influences that might "drive" aberrant behavior are addiction, pseudo-addiction (i.e., untreated pain[6]), self-medication of psychiatric or other physical symptoms, family dysfunction and criminality (i.e., intent to divert).[7]

The "norms" of drug taking and the epidemiology of aberrant drug-taking behavior have not been clearly established. Therefore, clinicians generally lack information to guide assessment of the severity of aberrant clinical occurrences. They might find a consensus of pain clinicians' views of drug taking a useful basis upon which to make their clinical interpretations on aberrancy. In other words, while patients can be individually given the benefit of the doubt in certain clinical circumstances involving even the most egregious of behaviors, the pain management community may be able to reach some level of agreement about what behaviors can routinely be excused and which ones cannot. Such agreement could serve as a basis for an individual clinician's decision-making so as to stay within the parameters of what the pain management community generally finds acceptable practice.

In an effort to ascertain the degree to which clinicians view the severity of specific aberrant drug-taking behaviors, we conducted a pilot survey of 100

pain physicians, asking them to rank order aberrant drug-taking behaviors for degree of aberrance.

MATERIALS AND METHODS

Procedures

A total of 100 physicians out of 147 total attendees completed a short survey on their perceptions of aberrant drug-taking behaviors. The physicians were attending the annual Janssen Pharmaceutica's Pain Experts Meeting in March 2001. The survey was conducted prior to the academic sessions and nearly all of those attending completed the questionnaire (124/147). Participants were asked to voluntarily complete the form as they registered for the meeting, were given verbal instructions for completing it, and asked to return it before the sessions began. Sessions during the meeting covered several relevant areas including assessment and pseudoaddiction.

Measure

The survey instrument was a seven-item questionnaire designed to gather demographic data on type of practice, years in practice, specific discipline, number of opioid prescriptions written per year, and the percentage of patients seen who have had previous substance abuse problems (Appendix). Specific information was not obtained on the respondents' training in addiction medicine.

The survey presented participants with a list of thirteen aberrant drug-taking behaviors (Table 1) that we have described extensively elsewhere[8] and asked that the respondents rank-order them from most aberrant to least aberrant. There was no contextualizing (i.e., placing the behaviors within a case) provided to the clinicians. Respondents were simply asked to rank the behaviors as compared to others on the list.

RESULTS

A total of 100 physicians completed the survey instrument prior to the meeting. These 100 represent the majority of those attending the meeting (100/147). Other attendees (n = 24) filled out the questionnaire but returned them after the sessions on addiction and were not included because they were not physicians and had no role in writing prescriptions for patients. No data are available on the non-responders (n = 23), including whether or not they were physicians. The majority (89.8%, n = 88) worked primarily in non-cancer pain manage-

TABLE 1. Mean Ranking of Aberrant Drug-Taking Behaviors According to Perceived Level of Severity

Rank	Aberrant Behavior	Mean	Standard Deviation
1	Selling prescription drugs	4.00	3.54
2	Forging prescriptions	4.47	3.64
3	Altering route or drug delivery system (i.e., crushing sustained-release tablets for snorting or injecting)	4.71	3.64
4	Concurrent abuse of related illicit drugs	5.10	2.89
5	Stealing or borrowing medications from others	5.22	2.98
6	Obtaining drug from non-medical source	5.79	3.02
7	Frequent prescription losses	6.18	2.67
8	Multiple unsanctioned dosing	7.42	2.86
9	Aggressive demand for more drug	7.61	3.38
10	Unapproved use of drug to treat non-pain symptoms	7.74	3.08
11	Drug hoarding	8.63	3.26
12	Unsanctioned dose escalation once or twice	9.79	3.60
13	Unkempt appearance	10.95	3.17

(1 = most severe behavior, 13 = least severe behavior) for the entire sample (n = 100).

ment while the remaining 10.2% (n = 10) stated that they worked primarily with cancer pain issues. For those working in non-cancer pain management, the respondents stated that the majority of their patients had either low back pain concerns (69.3%, n = 61) or musculoskeletal pain (22.7%, n = 20), while only 7 (8%) reported that the bulk of their patients had neurology-based pain. The specialty of the physician was most often found to be anesthesiology (49%, n = 49), primary care (21%, n = 21), or physiatry (15%, n = 15). The remainder of the sample was composed of specialists in oncology (8%, n = 8), psychiatry (4%, n = 4), neurology (2%, n = 2), and rheumatology (1%, n = 1).

A wide range of pain management experience was represented in the sample. Nearly a quarter of the physicians (24, 24.2%) had been in practice for over fifteen years and an additional 20 respondents (20.2%) had been clinically active for 11-15 years. Thirty-one (31.3%) had been in practice for 6 to 10 years. Less than a quarter (24, 24.2%) had been in practice for less than five years.

It also was of interest to determine the number of opioid prescriptions written per year as well as the percentage of patients being treated who had previ-

ous substance abuse issues. There was a wide range of opioid prescriptions written per year. Most respondents endorsed that they wrote from 1,001-5,000 prescriptions per year (43%, n = 43) followed by those reporting that they wrote between 501 and 1,000 per year (23%, n = 23). Seventeen reported writing more than 5,000 prescriptions per year (17%) while only 5% (n = 5) stated that they wrote less than 100 opioid prescriptions per year. Concerning the percentage of patients with previous substance abuse, most (66%, n = 66) reported that less than 10% of their patients had such problems followed by 28% (n = 28) who felt that 11-25% of their patients had abuse problems in the past. Only 6% (n = 6) felt that over 25% of their patients had prior substance abuse issues.

The primary goal of the questionnaire was to have the physicians rank-order thirteen aberrant drug-taking behaviors (listed in Table 1). Behaviors considered most aberrant were ranked with a '1' and those deemed least aberrant were ranked '13.' Interestingly each behavior elicited the full range of potential responses, i.e., the range was 1-13 for all of the items.

The thirteen aberrant drug-taking behaviors were examined to see what trends in perception, if any, emerged (Tables 1 and 2).

The sale of prescription drugs by patients had the lowest average rating (indicating greater aberrancy) (mean = 4.00, SD = 3.54) followed by the forging of prescriptions (mean = 4.47, SD = 3.64) and altering the route or delivery system of a drug (mean = 4.71, SD = 3.64). Having a patient appear as unkempt (mean = 10.95, SD = 3.17) had the highest average rating (indicating less aberrancy). Other behaviors toward the low end of aberrancy were the unsanctioned dose escalation of a drug once or twice (mean = 9.79, SD = 3.17) and the hoarding of drugs (mean = 8.63, SD = 3.60).

As a final step, a series of one-way analyses of variance (ANOVAs) were conducted to determine whether any of the demographic differences among physicians had a significant effect on the ranking of the aberrant drug-taking behaviors. Specifically, an ANOVA model was chosen to explore whether there was a clear relationship (or signal) standing out amongst the demographics regarding the rankings or if the demographic variables were simply not producing an effect (or adding noise). No significant differences in ranking were found based on the type of patients primarily seen, the number of years in practice, type of specialty, number of opioid prescriptions written per year, or based on the percentage of patients having previous substance abuse issues.

DISCUSSION

This pilot survey offers insight into the perceptions of 100 experienced physicians who are active in the pain management community. While the utilization of a convenience sample limits the conclusions one can draw from these

TABLE 2. Percentage of Times a Particular Behavior Occupied Each of the Rankings of Aberrancy

Percent rank for aberrant behaviors (1 = most severe behavior; 13 = least severe)												
1	2	3	4	5	6	7	8	9	10	11	12	13
Aggressive demand for more drug:												
5.9	3.4	5.0	5.9	6.7	3.4	10.1	12.6	8.4	14.3	12.6	9.2	2.5
Altering route or drug delivery system (i.e., crushing sustained-release tablets for snorting or injecting)												
26.1	13.4	7.6	7.6	10.1	8.4	5.9	5.0	0.8	6.7	1.7	2.5	4.2
Concurrent abuse of related illicit drugs												
12.5	11.7	8.3	11.7	15.0	11.7	7.5	5.8	5.8	4.2	3.3	2.5	0.0
Drug hoarding												
2.6	2.6	3.5	5.2	3.5	8.7	4.3	7.0	12.2	13.0	16.5	11.3	9.6
Forging prescriptions												
20.8	13.3	21.7	5.8	11.7	2.5	3.3	2.5	4.2	5.0	4.2	0.8	4.2
Frequent prescription losses												
1.7	2.5	4.2	9.2	10.0	14.2	13.3	15.8	8.3	6.7	0.8	2.5	0.8
Multiple unsanctioned dosing												
5.8	4.2	1.7	5.8	6.7	5.8	14.2	19.2	15.8	10.0	5.0	4.2	1.7
Obtaining drug from non-medical source												
7.6	8.4	8.4	10.9	10.9	14.3	8.4	7.6	8.4	6.7	5.9	0.8	1.7
Selling prescription drugs												
24.8	22.3	11.6	11.6	5.0	5.0	1.7	0.8	5.0	5.8	0.8	1.7	4.1
Stealing or borrowing medications from others												
7.5	6.7	19.2	15.0	10.8	7.5	9.2	7.5	6.7	4.2	4.2	0.8	0.8
Unapproved use of drug to treat non-pain symptoms												
4.2	2.5	5.0	4.2	9.2	10.1	13.4	9.2	10.1	10.9	6.4	10.9	1.7
Unkempt appearance												
3.4	0.8	0.8	3.4	0.8	1.7	2.5	2.5	0.0	3.4	12.6	24.4	43.7
Unsanctioned dose escalation once or twice												
4.2	2.5	2.5	2.5	4.2	2.5	0.8	4.2	5.0	10.9	17.6	21.8	21.0

(1 = most severe behavior; 13 = least severe behavior).

data, the results do offer insights into pain management physicians' feelings about aberrant drug-taking behaviors. No data was collected on the 23 attendees who did not respond. It is unknown why they failed to complete the survey. The potential exists that a certain type of physician was not examined, although it is impossible to determine what effect, if any, this has on the data.

Perhaps the most striking feature is that each aberrant behavior listed was ranked at each possible position (1-13) at least once, suggesting a great deal of variability among the perceptions of physicians. There is a great deal of personal history and experience that can color how an individual physician identifies the problem patient. For example, a physician who has never encountered a patient who has forged a prescription or sold drugs may have the feeling that such behavior is rare or not a factor. On the other hand, a physician who has been "burned" by a patient who has engaged in a particular aberrant behavior might have that behavior become very salient in their future assessments.

Along these lines, it would be helpful to know more about the specific addictionology training of the respondents. One can only assume in the absence of such data that these clinicians probably had the typical minimal training in addiction. These were experienced pain physicians with nearly half practicing for over 10 years and averaging between 19 and 96 prescriptions for opioids per week. While most of the practice demographic variables did not predict differences in rank order of the behaviors, differences in addiction medicine training might have done so and should be considered in future studies.

Despite the range of responses, an examination of the mean aberrancy ratings for the behaviors suggests a clustering of those behaviors that seemed to be viewed as more problematic. The respondent physicians viewed many of the illegal behaviors as the most aberrant, followed by altering route of administration. With the recent media reports of abuse and diversion of controlled release oxycodone, these behaviors, while infrequent, may have assumed a high profile in the consciousness of the public, law enforcement and physicians at the time this survey was performed. Interestingly, while criminality is viewed as the most problematic manifestation of aberrant drug taking behavior, such behaviors are often hard to prove and not readily apparent to clinicians. The detection of such behaviors requires excellent communication among physicians, pharmacists and other team members for monitoring. It is interesting to consider that physicians might view their role as predominantly tied to monitoring and responding to legal aspects of prescribing of controlled substances and that these issues may be even more salient to them than the more common medical and psychiatric aspects of aberrant behavior. Unkempt appearance, escalating a dose once or twice, and drug hoarding were all deemed to be less egregious offenses. Indeed these may arise primarily from poor pain control more often than they do addiction related concerns. The fact that the subse-

quent analyses (ANOVAs) failed to reveal significant differences between the physicians based on any of the demographic variables suggests that there very well may be some degree of agreement that transcend differences in experience and practice variables.

LIMITATIONS

The conclusions drawn from these results need to be made somewhat cautiously due to the small convenience sample employed and the fact that while all of these clinicians have an active interest in pain (they were all attending a meeting of a pharmaceutical company speaker's bureau) this does not necessarily suggest a particular expertise in aberrant behavior or generalizability to other pain clinicians. Further, the assessment instrument itself was limited and may have been better suited to ask physicians to rate the problematic behaviors separately on a 1-10 scale for more in-depth statistical analyses. Additionally, specific information on addiction medicine training and interest in aberrant behavior were not examined. Also, contextualization of these behaviors within a case format was not studied; perhaps the way these behaviors are viewed changes when pain, psychosocial and other aspects of a case example are provided. Finally, we do not have data from 23 clinicians (16%) who chose not to respond.

CONCLUSION

This pilot survey suggests that there is some consensus among physicians in their views of aberrant behavior with illegal behaviors topping the list. It is also interesting to note the large amount of individual variation in how these behaviors are viewed. Larger studies are needed to further clarify these issues and to help guide practicing clinicians according to a consensus of their colleagues.

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RECEIVED: 04/30/02
REVISED: 05/30/02
ACCEPTED: 06/04/02

APPENDIX

Assessment Survey Distributed to the Physicians

Profiling Research Questions
(Please circle your answers)

1. Which kind of pain represents the majority of your practice?
   A. Cancer Pain
   B. Non-cancer pain

2. If non-cancer pain, the majority is:
   A. Low back pain
   B. Musculoskeletal pain
   C. Other (please specify)_____

3. How many years have you been in pain practice?
   A. Less than 5
   B. 6-10
   C. 11-15
   D. 15+

4. What is your discipline?
   A. Psychiatry
   B. Anesthesiology
   C. Nursing
   D. Primary Care
   E. Oncology
   F. Other (please specify)_____

5. How many opioid prescriptions do you write per year?
   A. Fewer than 100
   B. 101-500
   C. 501-1000
   D. 1001-5000
   E. 5000+

6. What percentage of patients do you treat who have previous substance abuse issues?
   A. Less than 10%
   B. 11%-25%
   C. 26%-50%
   D. More than 50%

7. Please rank the following behaviors based on your perception of aberrant drug-taking behaviors in pain management from 1 for most aberrant to 13 for least aberrant.

   ___Aggressive demand for more drug
   ___Altering route or drug delivery system
   (i.e., crushing sustained-release tablets for snorting or injecting)
   ___Concurrent abuse of related illicit drugs
   ___Drug hoarding
   ___Forging prescriptions
   ___Frequent prescription losses
   ___Multiple unsanctioned dosing
   ___Obtaining drug from nonmedical source
   ___Selling prescription drugs
   ___Stealing or borrowing medications from others
   ___Unapproved use of drug to treat non-pain symptoms
   ___Unkempt appearance
   ___Unsanctioned dose escalation once or twice

1: J Pain Palliat Care Pharmacother. 2002;16(4):39-49.

Pain clinicians' rankings of aberrant drug-taking behaviors.

Passik SD, Kirsh KL, Whitcomb L, Dickerson PK, Theobald DE.

Chandler Medical College, and Marky Cancer Center, University of Kentucky, Lexington, KY 40536-0093, USA. spassik@uky.edu

A pilot study was conducted to examine experienced pain physicians' perceptions of aberrant drug taking behaviors. One hundred pain physicians attending a meeting on pain management were asked to rank order (from most aberrant = 1 to least aberrant = 13) a list of aberrant drug-taking behaviors. The sample was comprised mainly of anesthesiologists (50%) and half of the group had 10 or more years of pain management experience. The group prescribed an average of 19-96 opioid medications per week. Practice variables were not related to the rank ordering of the behaviors. All of the various behaviors appeared in all 13 of the rank ordering slots, suggesting a great deal of individual difference in the perception of these behaviors. By examining the average ranking of the behaviors, we noted that physicians' focus on illegal behaviors as the most aberrant followed by the alteration of route of delivery and self-escalation of dose. This survey suggests that an experienced group of pain clinicians does not view aberrant drug related behaviors uniformly. Average rankings suggest clinicians seem to view illegal behavior as the most worrisome. These results must be interpreted with caution due to the small convenience sample, the lack of data on the level of addiction medicine training of the respondents and the lack of data on those physicians who chose not to respond. Further inquiry could be used to guide clinicians' responses to aberrant behaviors when encountered in patients on controlled substances for pain.

PMID: 14635824 [PubMed - indexed for MEDLINE]

Prescription Pain Medications: Frequently Asked Questions and Answers for Health Care Professionals, and Law Enforcement Personnel

November 3, 2004

On October 6, the University of Wisconsin Pain & Policy Studies Group (PPSG) announced a communication we received from the Drug Enforcement Administration (DEA), in which we were informed by letter, dated October 4, 2004, that the DEA had rescinded it's endorsement of the recently publicized document, *Prescription Pain Medications: Frequently Asked Questions and Answers for Health Care Professionals and Law Enforcement Personnel* (FAQ). The DEA notified us that they had removed the FAQ from their website, citing that the document contained misstatements, and asked the PPSG to do likewise. The PPSG, along with several other organizations housing the FAQ, removed the document from their websites.

In response to this issue, members of the principal working group involved in the FAQ (Steven Passik, PhD; Russell Portenoy, MD; and David Joranson, MSSW) have written a letter to the DEA Administrator Karen Tandy. The letter asks that the DEA: (1) publicly reaffirm its commitment to achieving balance, (2) explain the misstatements in the FAQ so they can be addressed, (3) advise as to whether the agency plans to revive and disseminate the FAQ or a similar educational effort, and (4) tell how the agency proposes to restart a dialogue with the clinical community that is dedicated to pain management.

Both letters, and the PPSG's announcement, can be accessed through the links below.

October 4, 2004	October 6, 2004	October 26, 2004
PPSG receives letter from the DEA requesting removal of FAQ from our website	PPSG issues news alert regarding removal of FAQ from website	Russell Portenoy, Steven Passik, and David Joranson respond to the DEA

U. S. Department of Justice
Drug Enforcement Administration

www.dea.gov

Washington, D.C. 20537

OCT 0 4 2004

David E. Joranson, Director
Pain and Policy Studies Group
University of Wisconsin Comprehensive Cancer Center
406 Science Drive, Suite 202
Madison, Wisconsin 53711-1068

Dear Mr. Joranson:

This letter follows your telephone conversation with Patricia Good, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration (DEA). As Ms. Good informed you, DEA has become concerned that the document "Prescription Pain Medications: Frequently Asked Questions and Answers for Health Care Professionals, and Law Enforcement Personnel" contains misstatements of law and other statements which could create confusion about the applicable law and create misleading perceptions about physician's obligations to remain within the bounds of accepted medical practice. Accordingly, DEA has removed the document from its website pending further review of the document.

Pending completion of this review, DEA can no longer support or endorse the document. Accordingly, we request that you remove the document from your website, as well. The DEA will shortly be placing a statement on its website explaining the removal of the document.

The DEA appreciates your cooperation in this regard, and we regret any inconvenience.

Sincerely,

William J. Walker
Deputy Assistant Administrator
Office of Diversion Control

DEA removal of FAQ document

On August 11, 2004, the U.S. Drug Enforcement Administration (DEA), the Last Acts Partnership, and the University of Wisconsin Pain & Policy Studies Group (PPSG) released "Prescription Pain Medications: Frequently Asked Questions and Answers for Health Care Professionals, and Law Enforcement Personnel." The DEA has recently removed this document from their website and consequently has asked the PPSG to remove it from our site as well. Check the DEA's website for a statement explaining the removal of this document. We deeply regret any inconvenience this may cause.

Any questions should be directed to the DEA.

PAIN & POLICY STUDIES GROUP
WHO Collaborating Center
for Policy and Communications
in Cancer Care

October 26, 2004

The Honorable Karen Tandy
Administrator
Drug Enforcement Administration
2401 Jefferson Davis Highway
Alexandria, VA 22301

Dear Administrator Tandy,

We are members of the Principal Working Group that produced the *Frequently Asked Questions and Answers for Health Care Professionals and Law Enforcement Personnel* (FAQ) in cooperation with the DEA and many experts in pain management. Mr. Joranson received correspondence from William J. Walker on October 4, 2004, requesting him to remove the FAQ from the website of the University of Wisconsin Pain and Policy Studies Group. He removed it, on a temporary basis. Although Dr. Portenoy did not receive such a request, he too removed the FAQ from www.stoppain.org.

Our decisions to withdraw the document from our websites were made because of DEA's assertion that it contained "misstatements of law and other statements." However, we point out that numerous drafts were discussed with the DEA before the agency approved and publicly endorsed it. The answers in the FAQ (they are not guidelines) were based on the advice of experts and published information about medical management of pain and controlled substances policy. Relevant resources were listed after each question. Unfortunately, we have received no further clarification about the nature of the "misstatements," nor any indication of what the DEA proposes as the next steps to address the "misstatements."

The FAQ was intended to provide education to health care practitioners and law enforcement and regulatory personnel who are sometimes misinformed about pain management, abuse and addiction. Consequently, it is important to ask whether misstatements or misunderstandings led to the DEA's withdrawal of its support for the FAQ.

We believe it is critically important for the DEA to remain publicly committed to achieving the balanced approach to pain management and diversion, as expressed in the 2001 Joint Consensus Statement that DEA endorsed, and restated in the FAQ. Balance, according to the FAQ, means that in treating pain, health professionals should avoid contributing to diversion and drug abuse, and that enforcement efforts to control diversion must never interfere in clinical pain management. A balanced approach is not only consistent with but envisioned by federal law. There are growing concerns among health care professionals about the DEA's commitment to balance, and there are continuing concerns that people with pain are having difficulty finding health care professionals from whom to obtain needed medications.

The FAQ was a positive demonstration of the dialogue that is needed; it also gave substance to the view that clinicians and enforcement/regulatory authorities need education about pain management and controlled substances policy. The press conference releasing the FAQ was an important moment in this dialogue. The DEA's sudden withdrawal threatens to undermine several years of progress to further this

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dialogue and to educate clinicians about pain treatment, risk management and the legal considerations that are associated with the prescribing of controlled substances.

Accordingly, we ask that the DEA 1) publicly reaffirm its commitment to achieving balance, 2) explain the misstatements in the FAQ so they can be addressed, 3) advise as to whether the agency plans to revive and disseminate the FAQ or a similar educational effort, and 4) tell us how the agency proposes to restart a dialogue with the clinical community that is dedicated to pain management.

We look forward to your response and to continuing work with the DEA to achieve a balanced approach to diversion and pain management.

Sincerely

David E. Joranson
Senior Scientist, Director

Russell K. Portenoy, MD
Chairman, Department of Pain Medicine and Palliative Care
Beth Israel Medical Center
First Avenue at 16th St.
New York, NY 10003

Steven D. Passik, PhD
Director, Symptom Management and Palliative Care
Markey Cancer Center
University of Kentucky
Markey Cancer Center
800 Rose Street, CC449
Lexington, KY 40536-0093

Cc: William J. Walker, Deputy Assistant Administrator
Patricia Good, Chief, Liaison and Policy Section
FAQ Review Committee

Prescription Monitoring Programs

Presented by:

Michael A. Moné, JD, RPh
Pharmacy/Law Consultant

Richard K. Markuson, RPh
Executive Director
Idaho State Board of Pharmacy

Notes:

Resources

Presented by:

Robert Williamson
Senior Associate
Buzzeo/PDMA

Promoting Consistency in Regulation and Oversight of Pain Care

-Federation of State Medical Boards

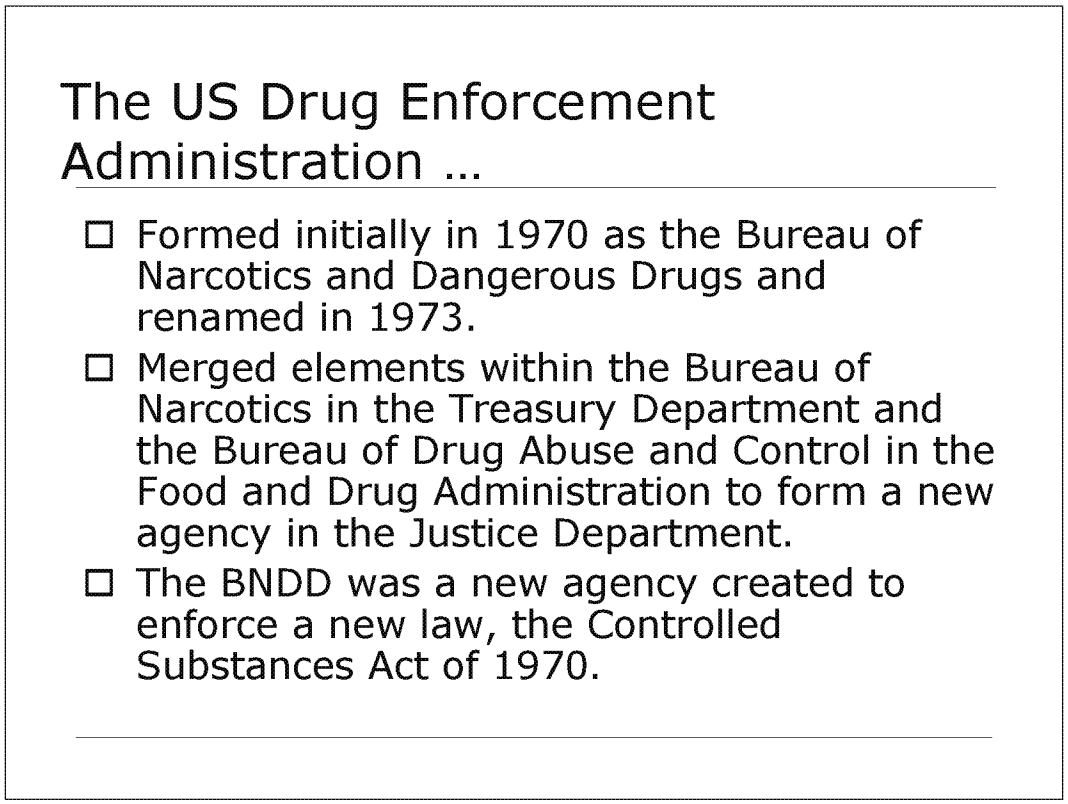
-2004-2005 Workshops

-Investigator Session – Other Law Enforcement Entities

-The Drug Enforcement Administration

-Presented by Robert C. Williamson

-Senior Associate, BuzzeoPDMA



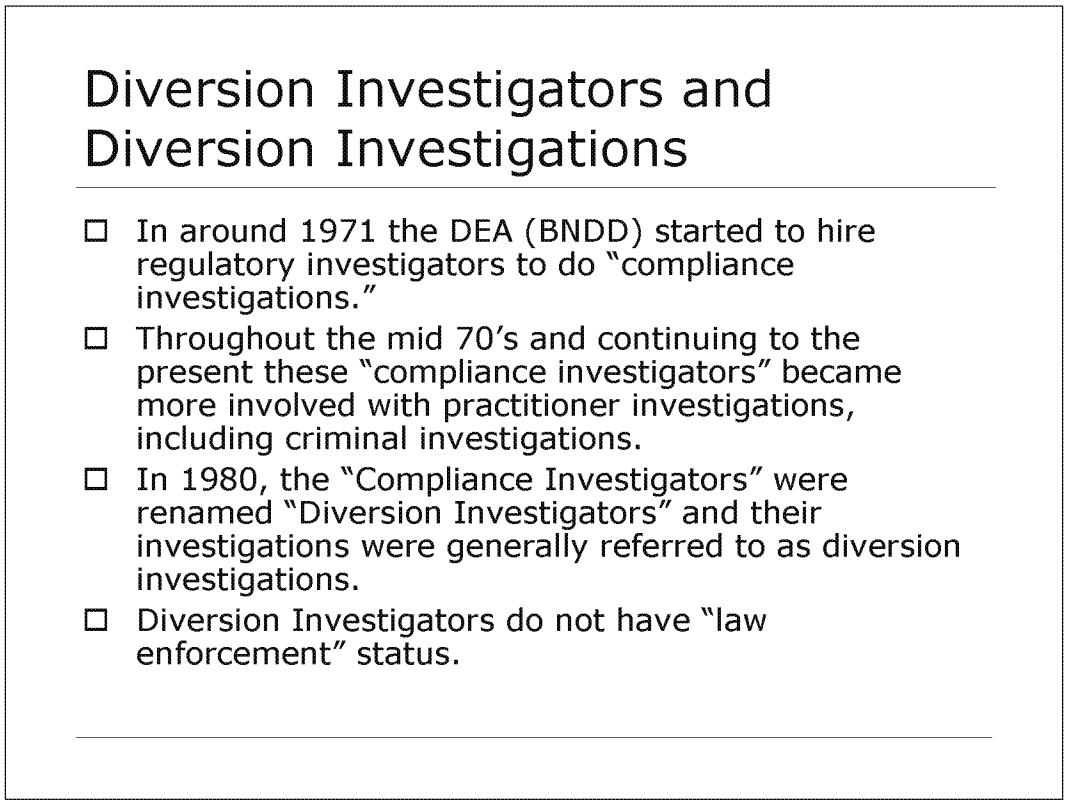
Learning objective:

Students should know that the Drug Enforcement Administration was formed in around 1970 to enforce a new federal law known as the Controlled Substances Act of 1970.

Pre and Post Test Question:

The Drug Enforcement Administration was formed in around 1970 to enforce the Controlled Substances Act. True or False?

Answer: True

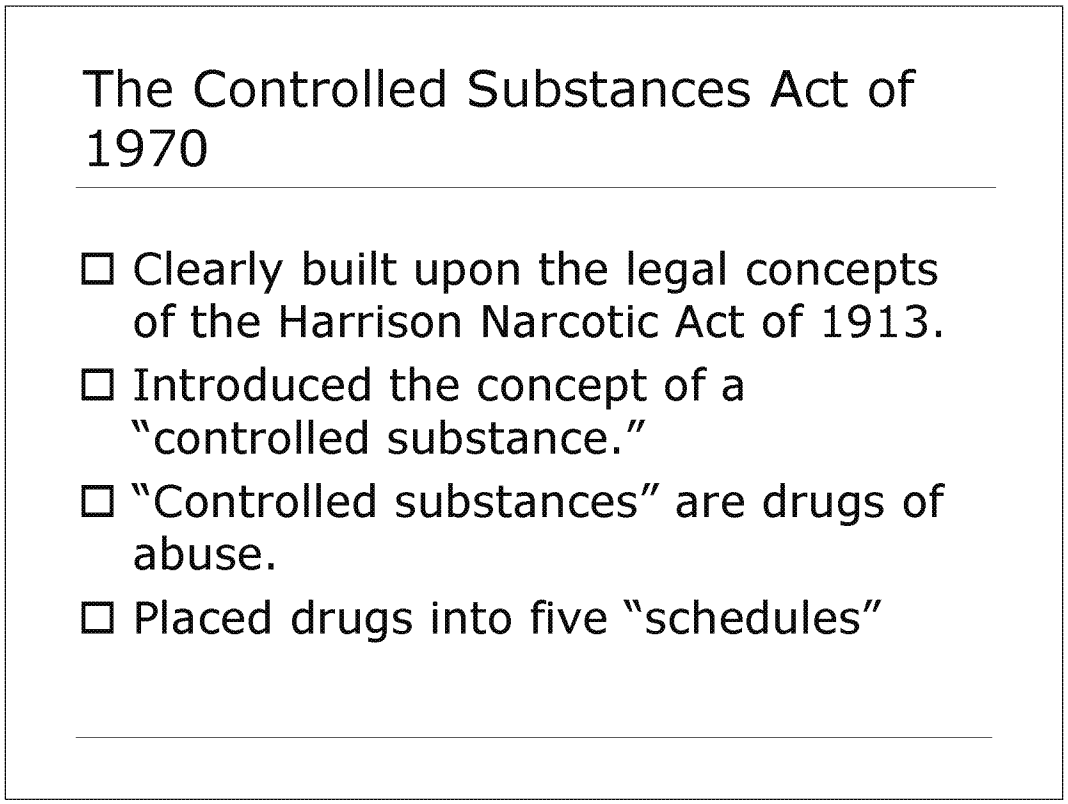


Learning objectives:

1. Students should know that DEA Diversion Investigators have training and expertise in federal drug regulations.
2. Students should know that DEA Diversion Investigators do not have law enforcement status.

Pre and Post Test Question:

1. If I wanted to know whether it was a violation of federal regulations to fax a prescription for a controlled substance to a pharmacy, I would call my local DEA office and ask for: a) a DEA Special Agent, b) the Special Agent in Charge, c) a DEA Diversion Investigator or d) the Group Assistant? **Answer:** c) DEA Diversion Investigators have training in federal controlled substance regulations.



Learning objectives:

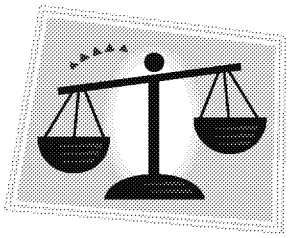
- Students must have a clear understanding of what a controlled substance is.
- Students must know that physicians must register with the DEA.

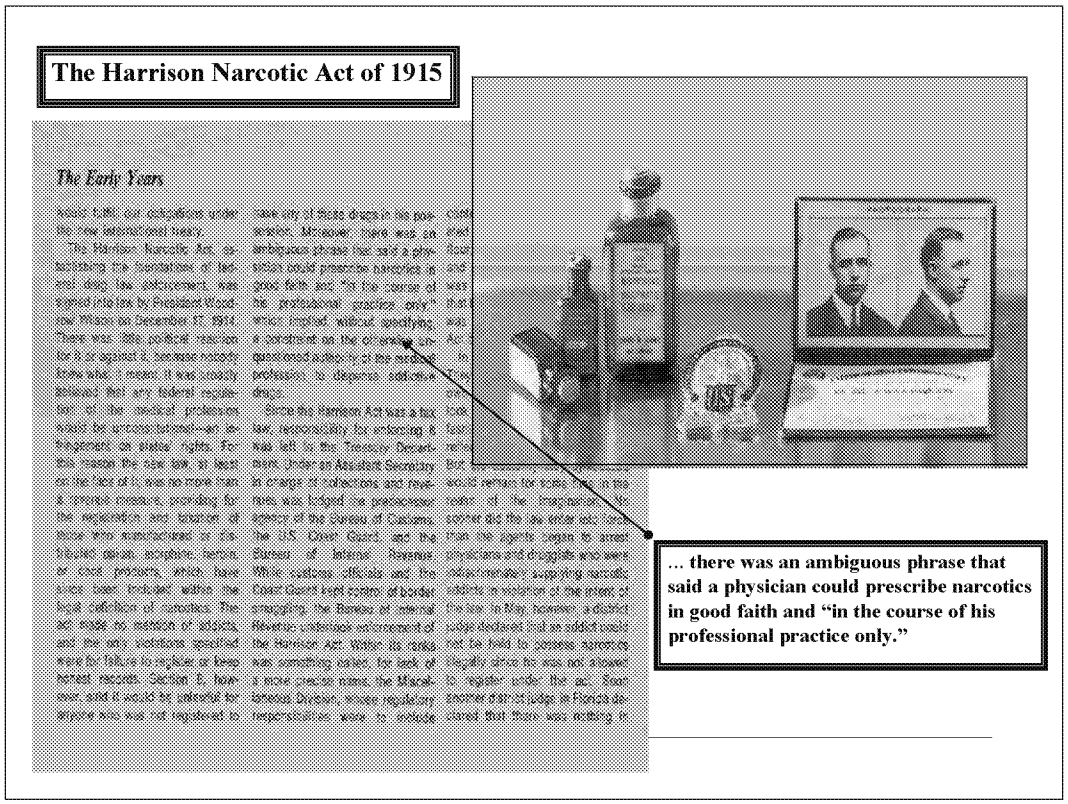
Pre and Post Test Questions:

- Would a prescription drug for birth control or high blood pressure be a "controlled substance?" Answer: No. Controlled substances are narcotics and other drugs of abuse.
- Does a physician need a DEA registration to prescribe high blood pressure medication? Answer: No. A DEA registration is only needed to prescribe controlled substances.

Professional Practice Cases Under the Law

- Physicians can legally dispense and prescribe controlled substances for a medical condition pursuant to a doctor/patient relationship.



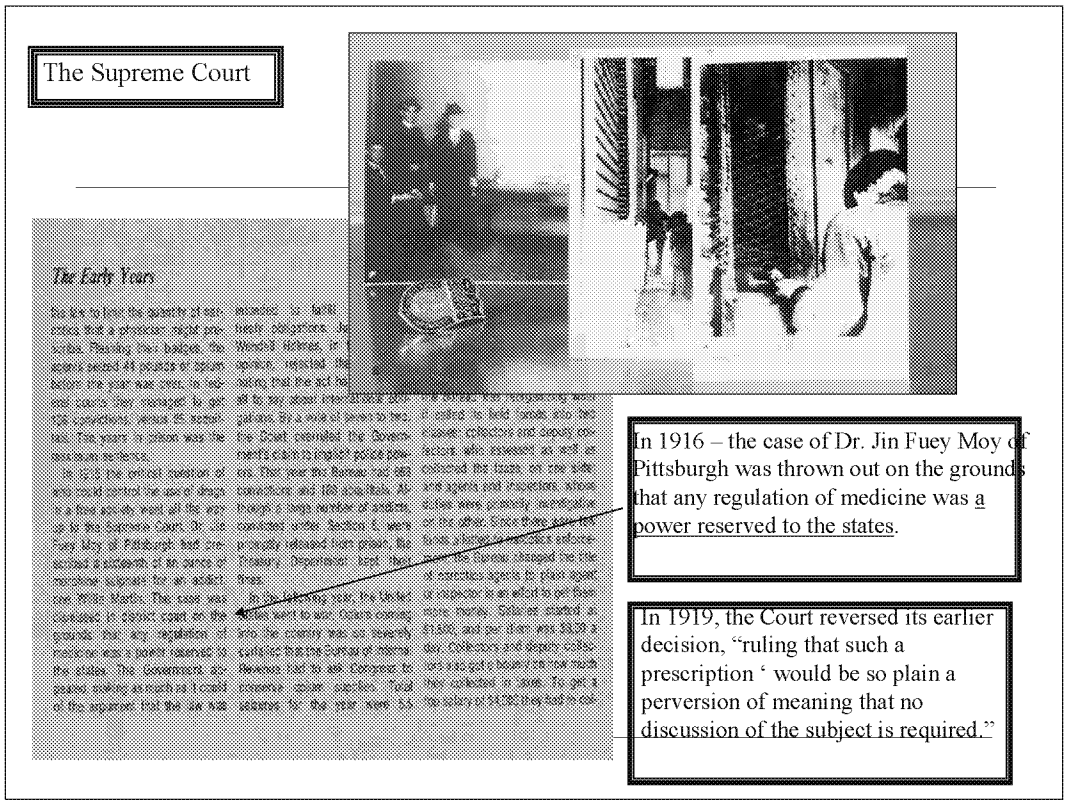


Learning objectives:

- The student should be familiar with the Harrison Narcotic Act of 1915.
- The student should know that this law established our fundamental policies affecting federal oversight for physician conduct.
- The student should be familiar with the concept of prescribing or dispensing pursuant to a legitimate medical need and pursuant to a bona fide physician/patient relationship.

Pre and Post Test Questions:

- Physicians have always been regulated by the federal government. True or False. **Answer:** False. The Harrison Narcotic Act of 1915 established federal oversight for physicians.
- Which of the following concepts or rules are contained in the Harrison Narcotic Act of 1915: 1) physicians cannot prescribe narcotics for patients beyond a 30 day period, 2) physicians can only prescribe narcotics in a hospital setting or 3) physicians can only prescribe narcotics in good faith and in the course of a professional practice. **Answer:** 3)



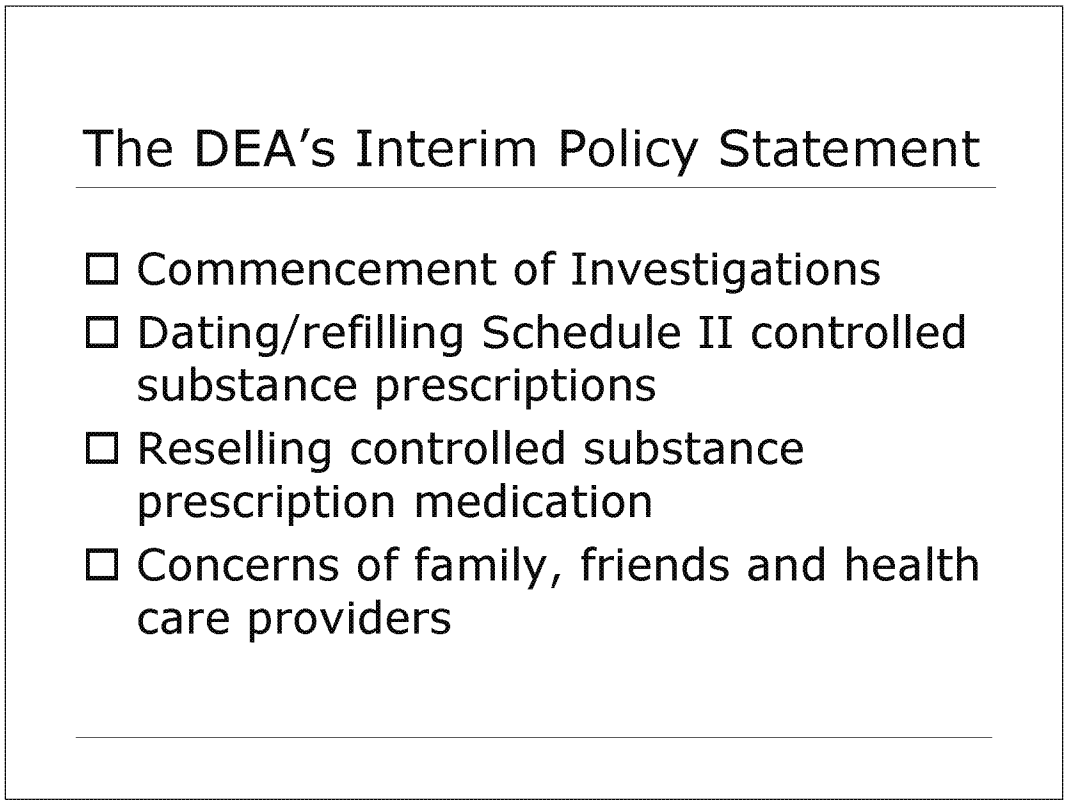
1. **Learning objectives:**
2. Students should know that the legal authority of the federal government in regulating physician conduct has been tested by the Supreme Court.
3. Students should know that the opinions of individual state medical boards have legal significance in federal laws and policies.

Pre and Post Test Question:

The legal authority of the federal government to investigate physicians regarding their prescribing of narcotic (opioids) drugs has been controversial almost from the outset and the subject of a Supreme Court opinion. True or False. **Answer:** True

Purpose of issue of prescription – 21 CFR 1306.04 (a)

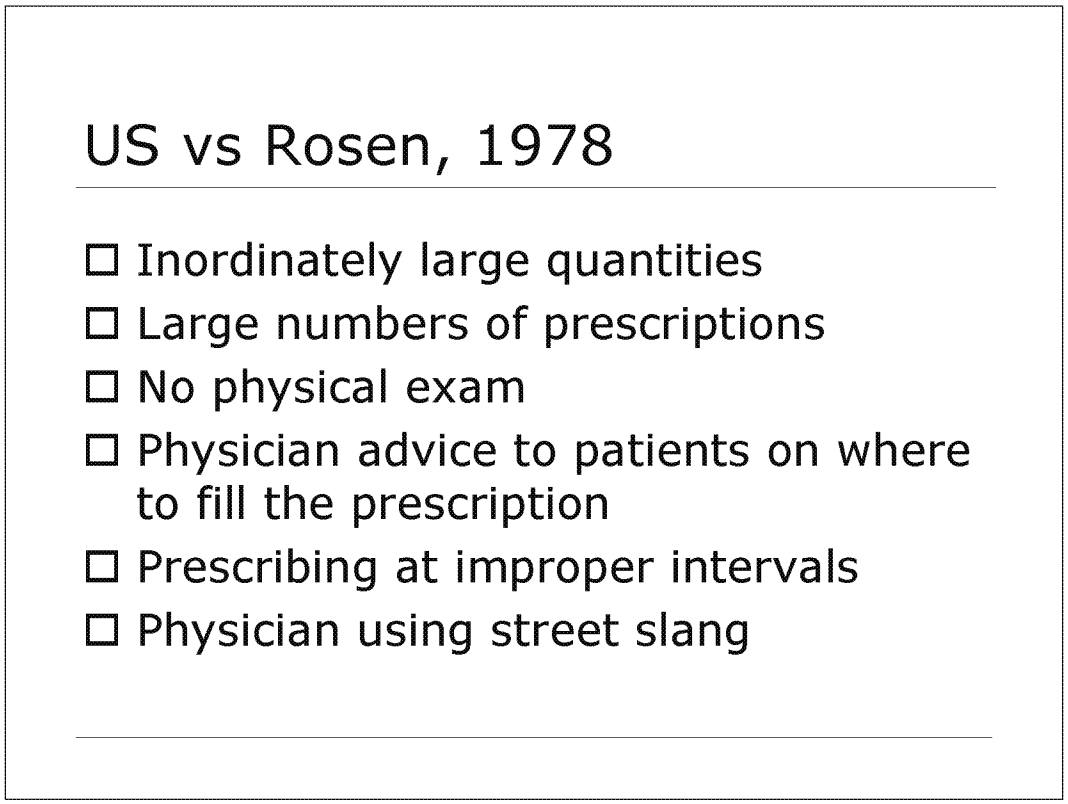
- A prescription for a controlled substance to be effective must be for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.



Learning objective: Students should have a good understanding of the issues and be prepared to offer sound advice to practitioners regarding the DEA's position on these four items.

Pre and Post Learning Questions:

1. It is permissible under federal law to write multiple prescriptions for Schedule II controlled substances and date them on the date that they are written with instructions to fill at later dates. True or False. Answer. False
2. From a DEA perspective, should a physician continue to treat a patient with additional opioids after the physician learns that the patient has illegally sold previous prescription medication? Answer. No



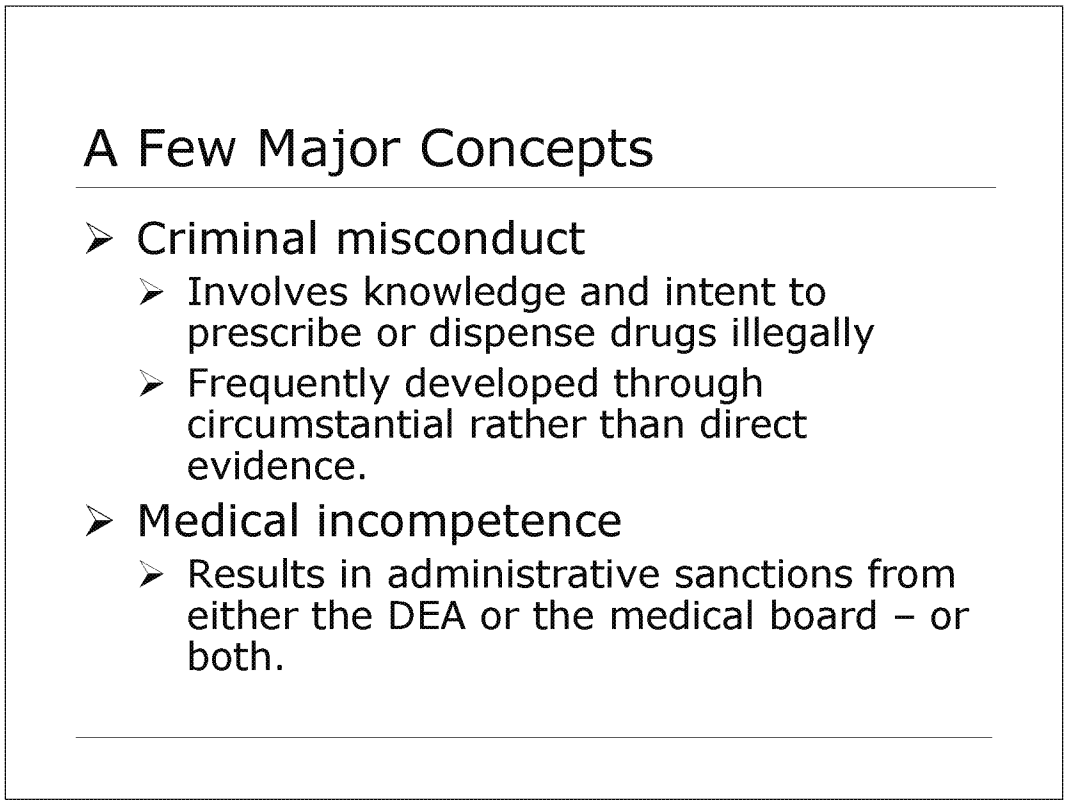
Learning objective: Students should especially understand that this case is important to the DEA because it was mentioned in the Interim Policy Statement.

Pre and Post Test Question:

1. Is there case law or a court opinion that the DEA appears to favor over others? Answer. Yes US v Rosen.
2. List out seven of the nine types of things that the Court found indicative of physician criminal behavior in US v Rosen.

US v Rosen, continued

- No logical connection between the drugs prescribed and the medical condition
- Writing multiple prescriptions to spread them out

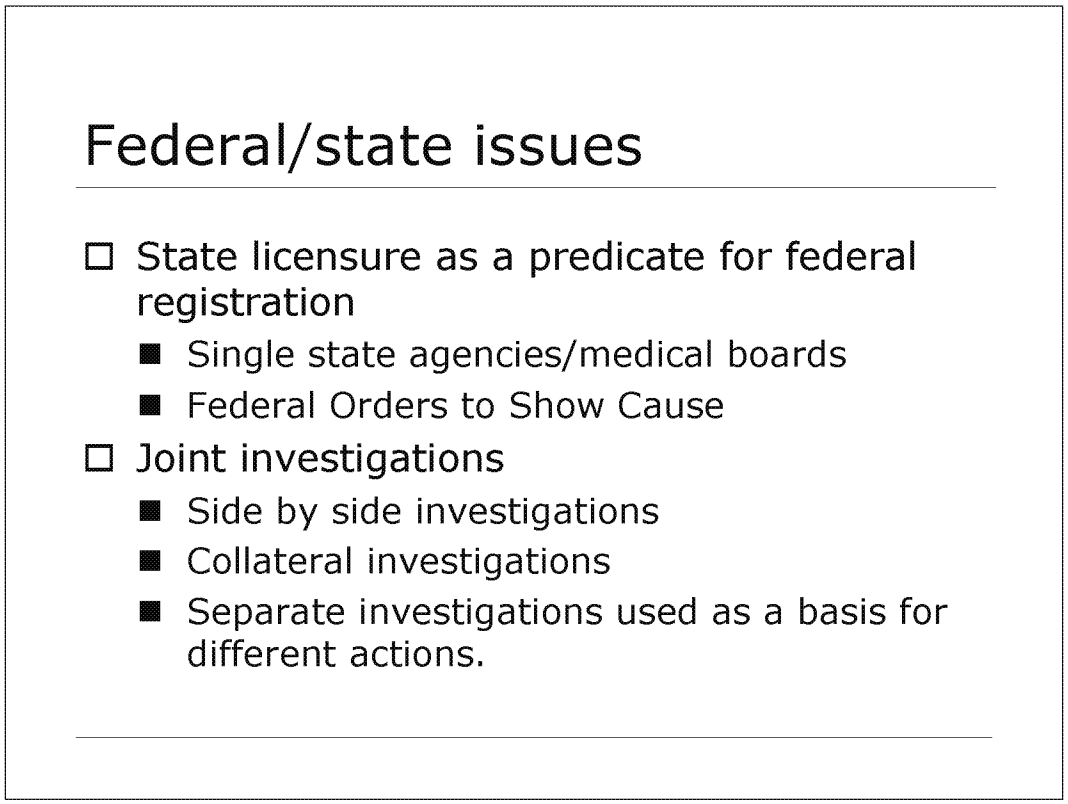


Learning objectives:

- Students should know that criminal prescribing includes the elements of knowing and intending to prescribe for an illegal purpose.
- Students should know that the most complaints do not end up in indictments.

Pre and Post Learning Questions:

- Most complaint investigations involving physicians result in an indictment? True or False. Answer: False
- Dr X is an elderly physician suffering from alcoholism and dementia. He prescribes opioids of all sorts for drug dealers and others without a proper medical examination. His office is a mess and he is clearly not making any money from prescribing drugs. Is he a suitable target for indictment? Answer: Probably not. He is incompetent and should loose his license.

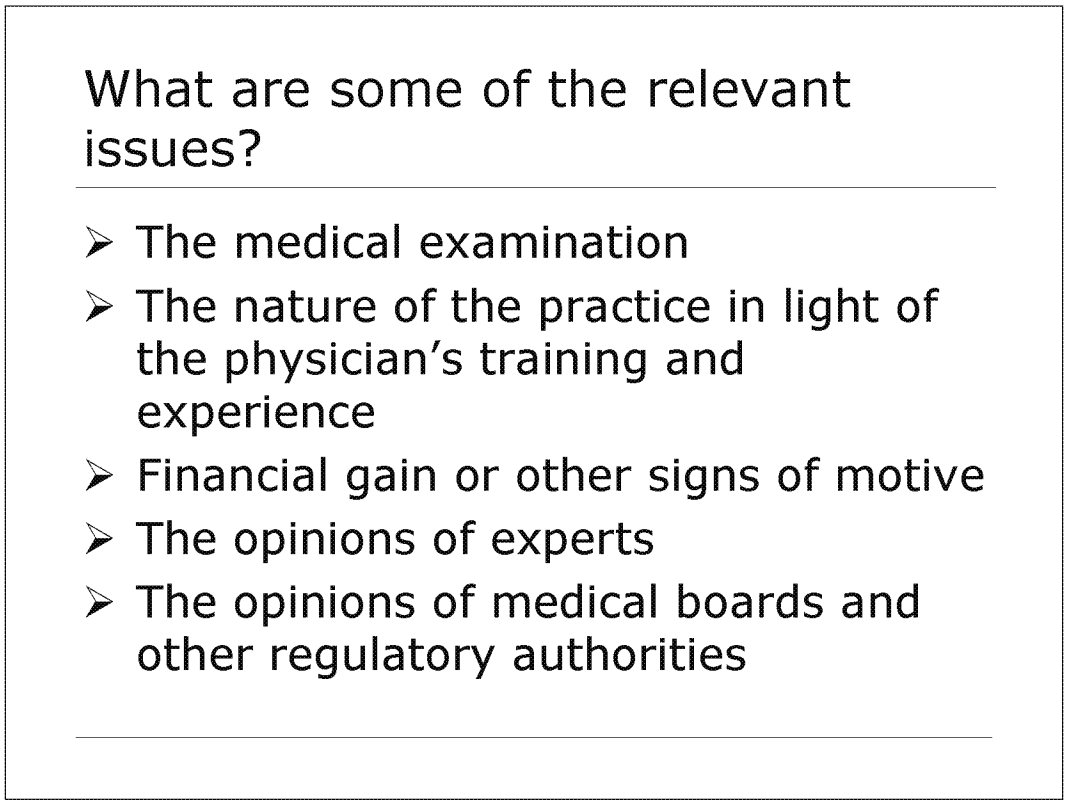


Learning objectives:

- Students should know that a federal DEA registration is predicated upon authority to prescribe or dispense controlled substances in the state or jurisdiction where the physician is located.
- Students should know that side by side investigations generally result in superior outcomes.
- Students should know that information sharing may be impossible when federal and state authorities conduct independent investigations.
- Students should know that separate investigations may be used as a basis for additional action by other agencies.

Pre and Post Learning Questions:

- Is it possible for a physician to keep his DEA registration after he or she has lost his or her license to practice medicine? Answer: A physician will have a right to a hearing; however, he or she will not be able to keep his or her DEA registration in the face of such a legal finding.
- When a medical board investigator is investigating a physician for criminal violations, what is the preferable type of investigative structure or organization? Answer: It is preferable to work closely with the DEA (or other law enforcement authority) so that information can be readily exchanged between and among the organizations, including attorneys and staff.



Learning objectives:

- Students should be able to list most of the major issues that need to be developed when conducting or exploring complaints of physician misconduct.
- Students should know that the quantities of drugs prescribed do not in and of themselves indicate wrongdoing.
- Students should know that the opinion of the medical board will be given higher weight or credibility when a case is evaluated in the federal arena.

Pre and Post Test Questions:

- List out three of the major issues that need to be resolved in physician investigations. **Answer:** Any of the following: the physician examination, the nature of the practice, financial gain, the opinions of experts, and the opinions of medical boards.
- A physician who is prescribing large quantities of narcotics should be investigated. True or False. **Answer:** False. Large quantities alone are not an adequate factor for initiating an investigation.
- Generally speaking the opinions of the state medical boards will be afforded greater weight and importance than other issues when physician cases are evaluated by federal authorities. True and False. **Answer:** True

Criminal cases – a few examples

The (Louisville, KY) Courier-Journal
October 20, 2002
Prescription for Abuse
Five Doctors at Clinic Allegedly Fed Addictions
By Gideon Gil

Dateline: SOUTH SHORE, Ky.
On Sept. 26, 2001, a South Shore doctor prescribed a painkiller, a tranquilizer and a muscle relaxant for Navy veteran Paul Bailey.

Physician Is Accused Of Violating Drug Laws (Post-Dispatch)

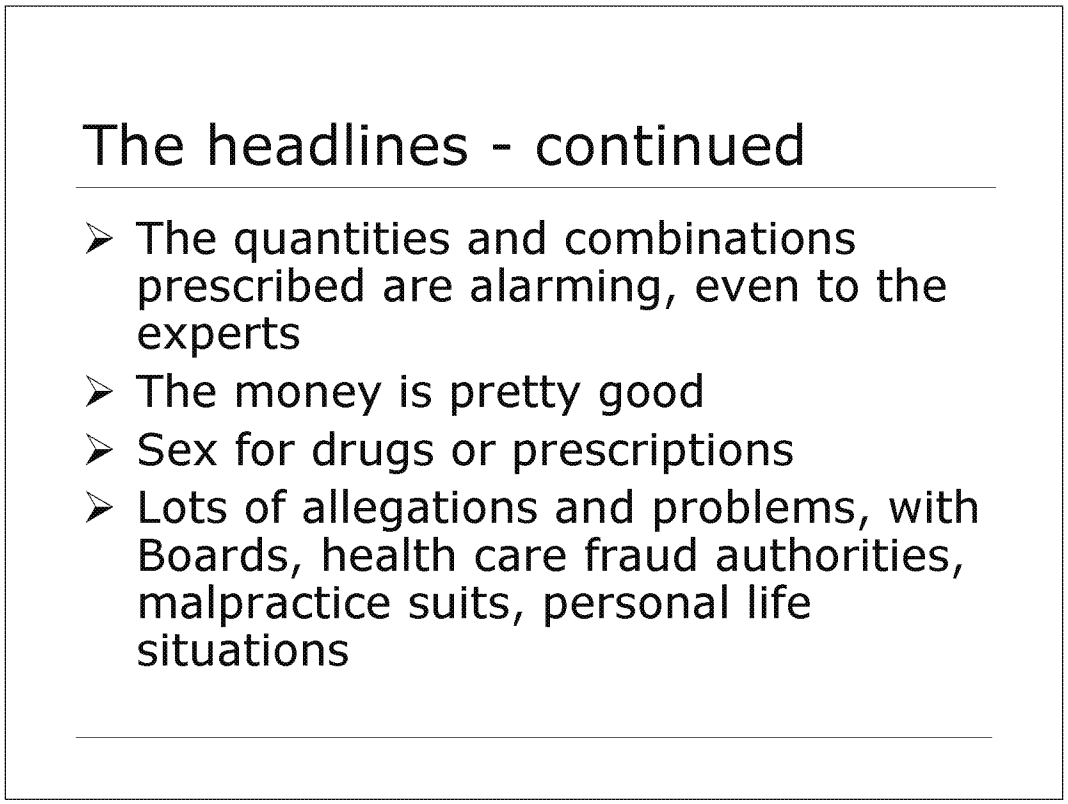
By Heather Ratcliffe

St. Louis Post-Dispatch, November 25, 2002

A physician in Bridgeton who specializes in pain management was arrested Monday on a 93-count indictment accusing him of selling prescriptions for the medical equivalent of cocaine, heroin, morphine and speed.

What's behind the headlines

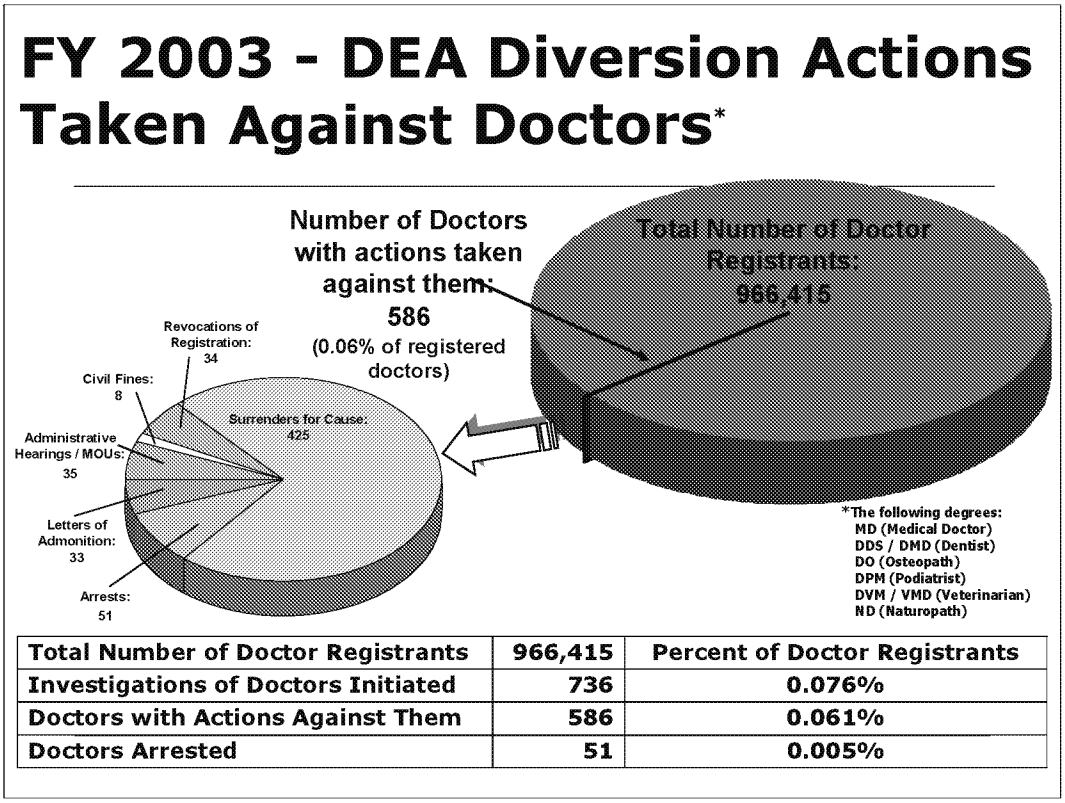
- Patients are dying – possibly (or probably) because of the drugs prescribed
- Patients are "tail gating" in the parking lot. Observers witness them doing drugs
- The police are making buys both in the office and in the parking lot
- The distances are suspicious
- And many of the "out of state" patients are implicated in illegal street sales



Learning objective: Students should have an understanding of the type of conduct that results in a criminal investigation pertaining to a physician.

Pre and Post Test Questions: For each of the following set of factual situations, please answer rather the conduct would be more likely associated with criminal conduct or less likely.

1. Physician Jones prescribes a lot of narcotics. She is located in a rural community where there are few physicians and the ones that are there have old established practices. Jones is a younger physician who has been active in learning more about adequate pain management. She has never been the subject of any disciplinary action in her home state or in any other state where she is licensed. **Answer:** Less likely.
2. Physician Smith prescribes a lot of narcotics. The police have been concerned because many of the drug dealers in town claim that Smith just writes prescriptions for cash. Observation of Smith's office discloses numerous out of state tags and an unbelievably heavy case load. Smith's medical license is restricted to Schedule III through V drugs due to a previous medical board investigation involving over prescribing. **Answer:** More likely.
3. Physician Brown has been prescribing Demerol to three "girl friends." They bring back a portion of the Demerol and use it recreationally with him. **Answer:** More likely.



Total Number of Doctor Registrants	966,415	Percent of Doctor Registrants
Investigations of Doctors Initiated	736	0.076%
Doctors with Actions Against Them	586	0.061%
Doctors Arrested	51	0.005%

Learning objectives:

1. Students should know that less than one percent of all registered practitioners will be investigated by the DEA.
2. Students should know that most DEA physician investigations result in an administrative action.

Pre and Post Test Questions:

1. About one in five physicians will be investigated by the DEA on an annual basis. True or False. **Answer:** False
2. Most DEA physician investigations do not really result in an indictment or an arrest, but some sort of lesser administrative sanction. True or False. **Answer:** True

FY 1999 to 2003 - DEA Diversion Actions Taken Against Doctors*

FULL YEAR DATA (BY FISCAL YEAR)	DRUG CRIMINAL/COMPLAINT INVESTIGATIONS			ACTIONS TAKEN AGAINST DOCTORS							NUMBER OF DOCTOR REGIS-TRANTS	PERCENT OF DOCTOR REGISTRANTS WHO:		
	TOTAL	INVESTIGA-TIONS OF DOCTORS	PERCENT	Arrests	Revocations of Registration (Code 2)	Surrenders for Cause (Code 1)	Civil Fines	Admin Hearings / MOUs	Letters of Admonition	TOTAL ACTIONS AGAINST DOCTORS		WERE INVESTI-GATED	ACTIONS WERE TAKEN AGAINST	WERE ARRESTED
FY 1999	1,787	926	51.82%	81	29	506	38	23	88	765	879,011	0.1053%	0.0870%	0.0092%
FY 2000	1,912	929	48.58%	83	15	548	24	36	77	783	897,953	0.1035%	0.0872%	0.0092%
FY 2001	1,769	861	48.67%	78	1	502	14	40	63	698	923,829	0.0932%	0.0756%	0.0084%
FY 2002	1,089	622	57.12%	68	11	415	10	34	30	568	939,363	0.0662%	0.0605%	0.0072%
FY 2003	1,479	736	49.76%	51	34	425	8	35	33	586	966,415	0.0762%	0.0606%	0.0053%

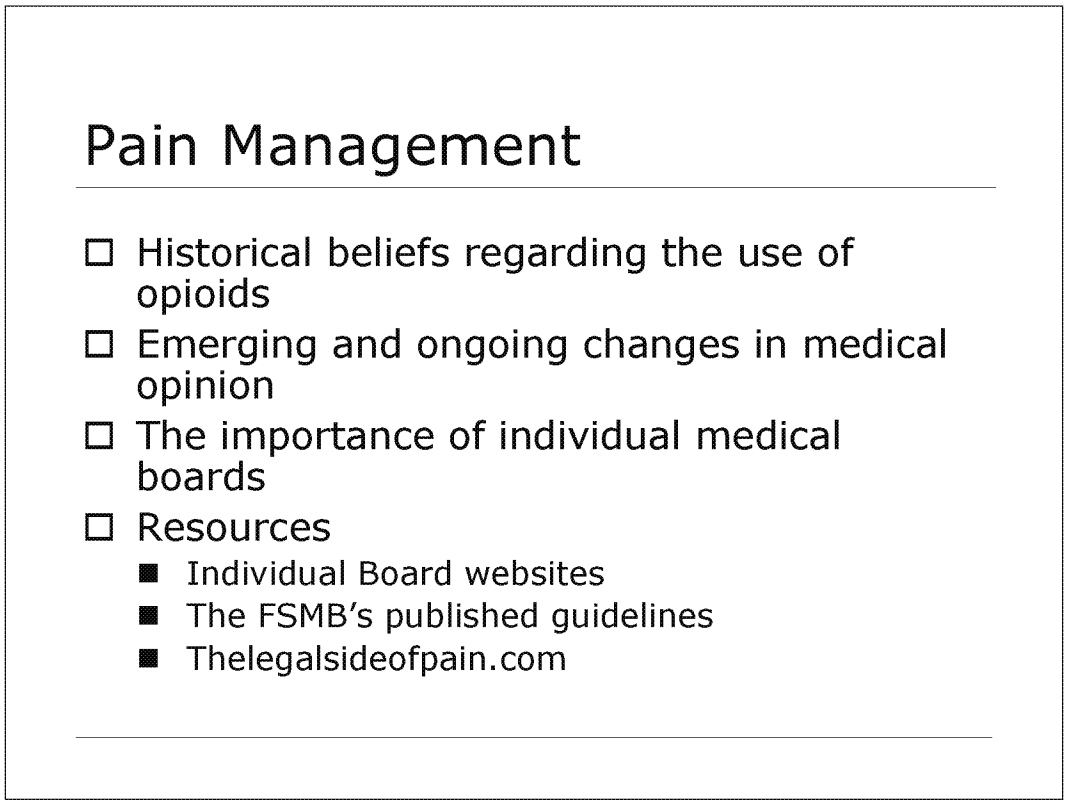
*The following degrees:
MD (Medical Doctor)
DDS / DMD (Dentist)
DO (Osteopath)
DPM (Podiatrist)
DVM / VMD (Veterinarian)
ND (Naturopath)

Learning objectives:

1. Students should know that the statistics describing the DEA's diversion investigation program have remained stable over time.
2. Students should know that physicians account for a significant percentage of the overall number of investigations conducted by DEA diversion investigators.

Pre and Post Learning Question:

1. The DEA primarily focuses its resources on investigating drug wholesalers and relies on the state medical authorities to investigate physician complaints. True or False. **Answer**: False



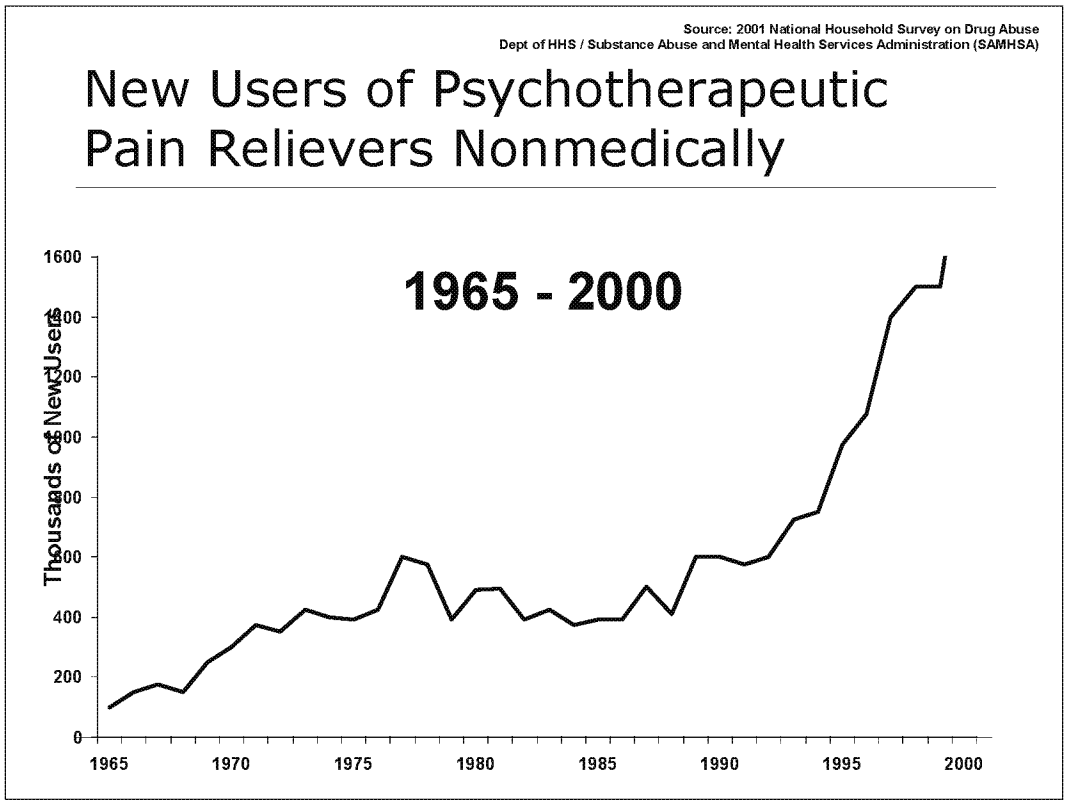
Learning objectives:

1. Students should have a general understanding of pain management issues.
2. Students should know that individual medical boards have different policies regarding pain management.
3. Students should be able to identify two resources for information regarding legitimate pain management.

Pre and Post Test Questions:

1. Medical boards are uniform in their policies for physician licensees. True or False. **Answer**: False
2. Name two resources for pain treatment information.

   Answer: Individual Board websites, The FSMB, The DEA's FAQ's and/or thelegalsideofpain.com

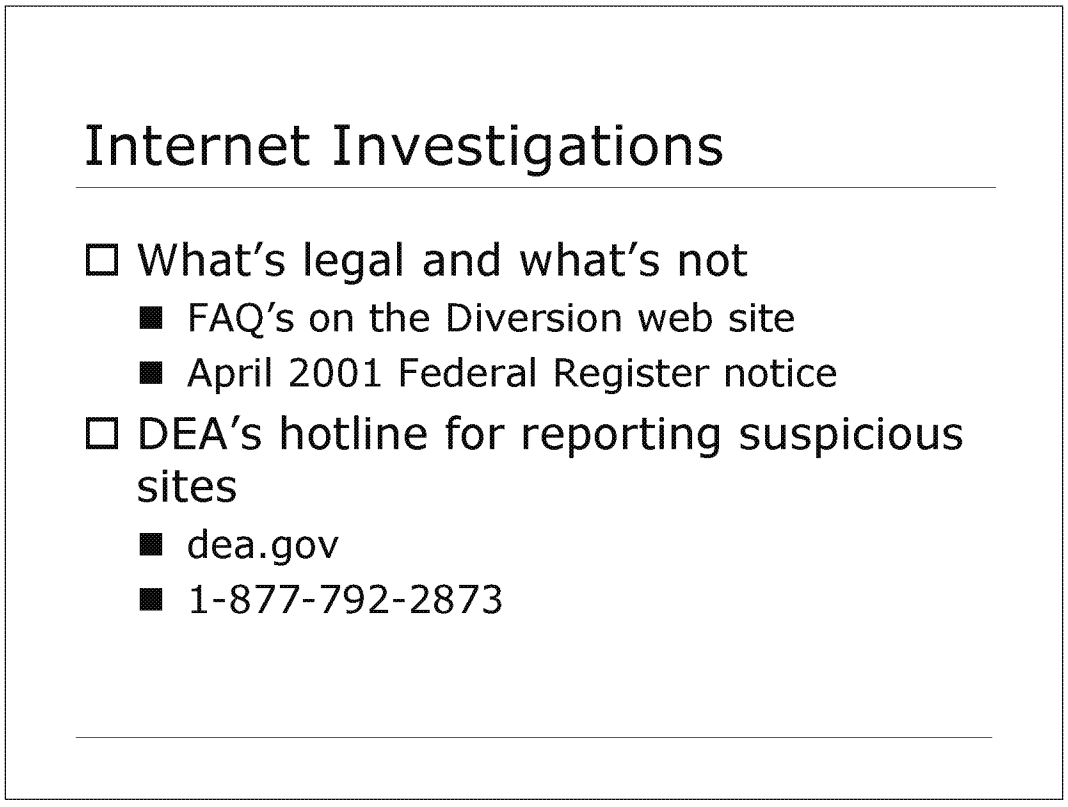


Learning objective:

Students should know that opioid abuse has been increasing significantly in recent years.

Pre and Post Test Question:

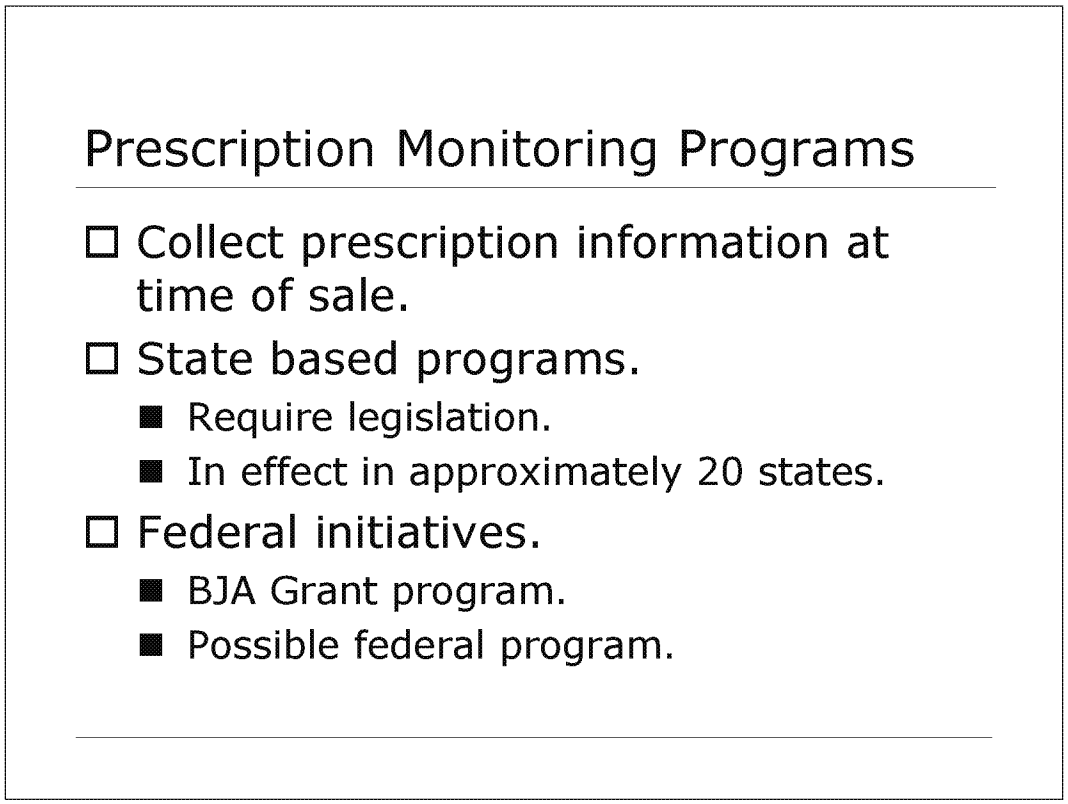
According to the Substance Abuse and Mental Health Services Administration (SAMHSA), trend information pertaining to opioid abuse has remained level or constant for many years. True or False. **Answer**: True



Learning objectives: Students should know that some internet activities are permissible and should be able to discern the major activities that are permissible and the ones that are not. Students should also know that the DEA will investigate internet complaints.

Pre and Post Test Questions:

1. Can a physician use e-mail to forward a legitimate prescription to my pharmacy. Answer. Only if a Schedule II prescription follows with the patient and only if a Schedule III, IV and V prescription is handled like an oral prescription.
2. Can I order controlled substances from overseas sources? Answer. No, only registered importers can order drugs from overseas sources.



Learning objectives:

1. Students should have an understanding of the term Prescription Monitoring Program and be able to describe what it is in conceptual terms.
2. Students should know that these are state programs.

Pre and Post Test Question:

Prescription Monitoring Programs are state programs that collect prescription information electronically at the point of sale and allow a state agency to review the information. True or False. **Answer**: True.

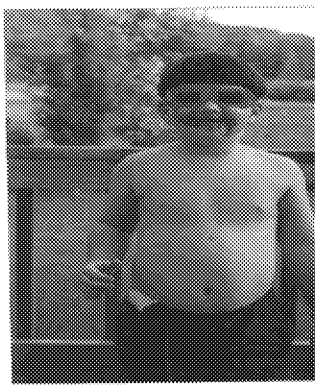
PMP Resources

- DEA FAQ's at deadiversion@usdoj.gov
- BJA Grants at ojp.usdoj.gov/BJA
- The National Association of State Controlled Substance Agencies at nascsa.org on left of home page.
- The National Alliance for Model State Drug Laws at natlalliance.org


U.S. Department of Justice
Drug Enforcement Administration
DIVERSION CONTROL PROGRAM
Welcome to the Diversion Control Program
Office of Diversion Control
Toll Free Registration Number: 1-800-882-9539
Please Read this Privacy and Security Statement
Contact Us

Not just another pretty face

- Questions???



Federation of State Medical Boards

Promoting Balance and Consistency in the Regulatory Oversight of Pain Care

Table of Contents

Appendix

Federation of State Medical Boards
of the United States, Inc.

MODEL POLICY FOR THE USE OF CONTROLLED SUBSTANCES FOR THE TREATMENT OF PAIN

Introduction

The Federation of State Medical Boards (the Federation) is committed to assisting state medical boards in protecting the public and improving the quality and integrity of health care in the United States. In 1997, the Federation undertook an initiative to develop model guidelines and to encourage state medical boards and other health care regulatory agencies to adopt policy encouraging adequate treatment, including use of opioids when appropriate for patients with pain. The Federation thanks the Robert Wood Johnson Foundation for awarding a grant in support of the original project, and the American Academy of Pain Medicine, the American Pain Society, the American Society of Law, Medicine, & Ethics, and the University of Wisconsin Pain & Policy Studies Group for their contributions.

Since adoption in April 1998, the *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* have been widely distributed to state medical boards, medical professional organizations, other health care regulatory boards, patient advocacy groups, pharmaceutical companies, state and federal regulatory agencies, and practicing physicians and other health care providers. The *Model Guidelines* have been endorsed by the American Academy of Pain Medicine, the Drug Enforcement Administration, the American Pain Society, and the National Association of State Controlled Substances Authorities. Many states have adopted pain policy using all or part of the *Model Guidelines.*[1] Despite increasing concern in recent years regarding the abuse and diversion of controlled substances, pain policies have improved due to the efforts of medical, pharmacy, and nursing regulatory boards committed to improving the quality of and access to appropriate pain care.

Notwithstanding progress to date in establishing state pain policies recognizing the legitimate uses of opioid analgesics, there is a significant body of evidence suggesting that both acute and chronic pain continue to be undertreated. Many terminally ill patients unnecessarily experience moderate to severe pain in the last weeks of life.[2] The undertreatment of pain is recognized as a serious public health problem that results in a decrease in patients' functional status and quality of life and may be attributed to a myriad

[1] As of January 2004, 22 of 70 state medical boards have policy, rules, regulations or statutes reflecting the Federation's *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* and two (2) states have formally endorsed the *Model Guidelines*.

[2] SUPPORT Study Principal Investigators. A controlled trial to improve care for seriously ill hospitalized patients: *JAMA*, 274(20) (1995): p. 1591-1598.

of social, economic, political, legal and educational factors, including inconsistencies and restrictions in state pain policies.[3] Circumstances that contribute to the prevalence of undertreated pain include: (1) lack of knowledge of medical standards, current research, and clinical guidelines for appropriate pain treatment; (2) the perception that prescribing adequate amounts of controlled substances will result in unnecessary scrutiny by regulatory authorities; (3) misunderstanding of addiction and dependence; and (4) lack of understanding of regulatory policies and processes. Adding to this problem is the reality that the successful implementation of state medical board pain policy varies among jurisdictions.

In April 2003, the Federation membership called for an update to its *Model Guidelines* to assure currency and adequate attention to the undertreatment of pain. The goal of the revised model policy is to provide state medical boards with an updated template regarding the appropriate management of pain in compliance with applicable state and federal laws and regulations. The revised policy notes that the state medical board will consider inappropriate treatment, including the undertreatment of pain, a departure from an acceptable standard of practice. The title of the policy has been changed from *Model Guidelines* to *Model Policy* to better reflect the practical use of the document.

The *Model Policy* is designed to communicate certain messages to licensees: that the state medical board views pain management to be an important and integral to the practice of medicine; that opioid analgesics may be necessary for the relief of pain; that the use of opioids for other than legitimate medical purposes pose a threat to the individual and society; that physicians have a responsibility to minimize the potential for the abuse and diversion of controlled substances; and that physicians will not be sanctioned solely for prescribing opioid analgesics for legitimate medical purposes. In addition, this policy is not meant to constrain or dictate medical decision-making.

Through this initiative, the Federation aims to achieve more consistent policy in promotion of adequate pain management and education of the medical community about treating pain within the bounds of professional practice and without fear of regulatory scrutiny. In promulgating this *Model Policy*, the Federation strives to encourage the legitimate medical uses of controlled substances for the treatment of pain while stressing the need to safeguard against abuse and diversion.

State medical boards are encouraged, in cooperation with their state's attorney general, to evaluate their state pain policies, rules, and regulations to identify any regulatory restrictions or barriers that may impede the effective use of opioids to relieve pain. Accordingly, this *Model Policy* has been revised to emphasize the professional and ethical responsibility of the physician to assess patients' pain and update references and definitions of key terms used in pain management.

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[3] A.M. Gilson, D.E. Joranson, and M.A. Mauer, Improving Medical Board Policies: Influence of a Model, *J. of Law, Medicine, and Ethics*, 31 (2003): p. 128.

The *Model Policy* is not intended to establish clinical practice guidelines nor is it intended to be inconsistent with controlled substance laws and regulations.

Model Policy for the Use of Controlled Substances for the Treatment of Pain

Section I: Preamble

The (name of board) recognizes that principles of quality medical practice dictate that the people of the State of (name of state) have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. For the purposes of this policy, the inappropriate treatment of pain includes nontreatment, undertreatment, overtreatment, and the continued use of ineffective treatments.

The diagnosis and treatment of pain is integral to the practice of medicine. The Board encourages physicians to view pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially urgent for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about assessing patients' pain and effective methods of pain treatment, as well as statutory requirements for prescribing controlled substances. Accordingly, this policy have been developed to clarify the Board's position on pain control, particularly as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

Inappropriate pain treatment may result from physicians' lack of knowledge about pain management. Fears of investigation or sanction by federal, state and local agencies may also result in inappropriate treatment of pain. Appropriate pain management is the treating physician's responsibility. As such, the Board will consider the inappropriate treatment of pain to be a departure from standards of practice and will investigate such allegations, recognizing that some types of pain cannot be completely relieved, and taking into account whether the treatment is appropriate for the diagnosis.

The Board recognizes that controlled substances including opioid analgesics may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer

origins. The Board will refer to current clinical practice guidelines and expert review in approaching cases involving management of pain. The medical management of pain should consider current clinical knowledge and scientific research and the use of pharmacologic and non-pharmacologic modalities according to the judgment of the physician. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity, duration of the pain, and treatment outcomes. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction.

The (name of board) is obligated under the laws of the State of (name of state) to protect the public health and safety. The Board recognizes that the use of opioid analgesics for other than legitimate medical purposes pose a threat to the individual and society and that the inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Accordingly, the Board expects that physicians incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.

Physicians should not fear disciplinary action from the Board for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice. The Board will consider prescribing, ordering, dispensing or administering controlled substances for pain to be for a legitimate medical purpose if based on sound clinical judgment. All such prescribing must be based on clear documentation of unrelieved pain. To be within the usual course of professional practice, a physician-patient relationship must exist and the prescribing should be based on a diagnosis and documentation of unrelieved pain. Compliance with applicable state or federal law is required.

The Board will judge the validity of the physician's treatment of the patient based on available documentation, rather than solely on the quantity and duration of medication administration. The goal is to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors.

Allegations of inappropriate pain management will be evaluated on an individual basis. The board will not take disciplinary action against a physician for deviating from this policy when contemporaneous medical records document reasonable cause for deviation. The physician's conduct will be evaluated to a great extent by the outcome of pain treatment, recognizing that some types of pain cannot be completely relieved, and by taking into account whether the drug used is appropriate for the diagnosis, as well as improvement in patient functioning and/or quality of life.

Section II: Guidelines

The Board has adopted the following criteria when evaluating the physician's treatment of pain, including the use of controlled substances:

1. **Evaluation of the Patient—**A medical history and physical examination must be obtained, evaluated, and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.
2. **Treatment Plan—**The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.
3. **Informed Consent and Agreement for Treatment—**The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is without medical decision-making capacity. The patient should receive prescriptions from one physician and one pharmacy whenever possible. If the patient is at high risk for medication abuse or has a history of substance abuse, the physician should consider the use of a written agreement between physician and patient outlining patient responsibilities, including
    a. urine/serum medication levels screening when requested;
    b. number and frequency of all prescription refills; and
    c. reasons for which drug therapy may be discontinued (e.g., violation of agreement).
4. **Periodic Review—**The physician should periodically review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health. Continuation or modification of controlled substances for pain management therapy depends on the physician's evaluation of progress toward treatment objectives. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Objective evidence of improved or diminished function should be monitored and information from family members or other caregivers should be considered in determining the patient's response to treatment. If the patient's progress is unsatisfactory, the physician should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.
5. **Consultation—**The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be

given to those patients with pain who are at risk for medication misuse, abuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

6. **Medical Records—**The physician should keep accurate and complete records to include
    a. the medical history and physical examination,
    b. diagnostic, therapeutic and laboratory results,
    c. evaluations and consultations,
    d. treatment objectives,
    e. discussion of risks and benefits,
    f. informed consent,
    g. treatments,
    h. medications (including date, type, dosage and quantity prescribed),
    i. instructions and agreements and
    j. periodic reviews.

    Records should remain current and be maintained in an accessible manner and readily available for review.

7. **Compliance With Controlled Substances Laws and Regulations—**To prescribe, dispense or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state regulations. Physicians are referred to *the Physicians Manual of the U.S. Drug Enforcement Administration* and (any relevant documents issued by the state medical board) for specific rules governing controlled substances as well as applicable state regulations.

Section III: Definitions

For the purposes of these guidelines, the following terms are defined as follows:

Acute Pain—Acute pain is the normal, predicted physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease. It is generally time-limited.

Addiction—Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

Chronic Pain—Chronic pain is a state in which pain persists beyond the usual course of an acute disease or healing of an injury, or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

Pain—An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Physical Dependence—Physical dependence is a state of adaptation that is manifested by drug class-specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist. Physical dependence, by itself, does not equate with addiction.

Pseudoaddiction—The iatrogenic syndrome resulting from the misinterpretation of relief seeking behaviors as though they are drug-seeking behaviors that are commonly seen with addiction. The relief seeking behaviors resolve upon institution of effective analgesic therapy.

Substance Abuse—Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

Tolerance—Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect, or a reduced effect is observed with a constant dose over time. Tolerance may or may not be evident during opioid treatment and does not equate with addiction.

Appendix H
Model Prescription Monitoring Act

Section 1. Short Title.

This Act shall be known and may be cited as the "Model Prescription Monitoring Act."

Section 2. Legislative Findings.

(insert state-appropriate mission/purposes)

Section 3. Purpose.

(insert state-appropriate mission/purposes)

Section 4. Definitions.

(a) "Advisory Board" means the advisory board established under Section 6 of this Act.

(b) "Dispenser" means a person authorized in this state to distribute to the ultimate user a substance monitored by the prescription monitoring program, but does not include:

(1) a licensed hospital pharmacy that distributes such substances for the purposes of inpatient hospital care or the dispensing of prescriptions for controlled substances at the time of discharge from such a facility.

(2) a licensed nurse or medication aide who administers such a substance at the direction of a licensed physician; or

(3) a wholesale distributor of a substance monitored by the prescription monitoring program.

(c) "Prescriber" means a licensed health care professional with prescriptive authority.

(d) "Prescription Monitoring Information" means information submitted to and maintained by the Prescription Monitoring Program.

(e) "Prescription Monitoring Program (PMP)" means a program established under Section 5 of this Act.

Section 5. Establishment Of A Prescription Monitoring Program.

(a) The Board of Pharmacy (or designated state agency or entity) shall establish and maintain, with the consultation of the Advisory Board, an electronic system for monitoring the following substances dispensed in the state: (insert all or any combination of the following: Federally controlled substances, additional state-specified controlled substances, and Drugs of concern documented to demonstrate a potential for abuse, particularly those identified by law enforcement and addiction treatment professionals).

(b) The Board of Pharmacy (or designated state agency or entity) may contract with a vendor to establish and maintain the electronic monitoring system pursuant to guidelines which the Board of Pharmacy (or designated state agency or entity) shall promulgate.

Section 6. Advisory Board.

(a) The Advisory Board shall have the following members:

(1) (insert appropriate designees of state health, law enforcement, and prosecutorial agencies)

(2) (insert appropriate designees of occupational licensing, certification, and regulatory entities)

(3) (insert appropriate designees of impaired professionals programs)

(4) (insert appropriate pain management and addiction treatment representatives)

(5) (insert appropriate patient rights advocates)

(6) (insert appropriate recovering community advocates)

(7) (insert appropriate community leaders)

(b) The Board of Pharmacy (or designated state agency or entity) shall seek, and the Advisory Board shall provide, input and advice regarding the development and operations of the electronic monitoring system, including but not limited to:

(1) Which state controlled substances should be monitored,

(2) Which Drugs of concern demonstrate a potential for abuse and should be monitored,

(3) The design and implementation of educational courses identified in Section 9,

(4) Proper analysis and interpretation of prescription monitoring information,

(5) The design and implementation of an evaluation component, and

(6) Potential nominees to the Advisory Board.

Section 7. Reporting Of Prescription Monitoring Information.

(a) Each Dispenser shall submit to the Board of Pharmacy (or designated state agency or entity), by electronic means, or other format specified in a waiver granted by the Board of Pharmacy (or designated state agency or entity), information specified by the Board of Pharmacy (or designated state agency or entity), including:

(1) A patient identifier,

(2) The Drug Dispensed,

(3) The date of the Dispensing,

(4) The quantity Dispensed,

(5) The Prescriber, and

(6) The Dispenser.

(b) Each Dispenser shall submit the required information as frequently as specified by the Board of Pharmacy (or designated state agency).

(c) The Board of Pharmacy (or designated state agency or entity) may grant a waiver of electronic submission to any Dispenser for good cause, including financial hardship, as determined by the Board of Pharmacy (or designed state agency or entity). The waiver shall state the format and frequency with which the Dispenser shall submit the required information.

Section 8. Access To Prescription Monitoring Information/Confidentiality.

(a) Except as indicated in paragraphs (b), (c), and (d) of this Section 8, Prescription Monitoring Information submitted to the Board of Pharmacy (or designated state agency or entity) shall be considered Protected Health Information and not subject to public or open records laws.

(b) The Board of Pharmacy (or designated state agency or entity) shall review the Prescription Monitoring Information. If there is reasonable cause to believe a violation of law (or breach of occupational standards) may have occurred, the Board (or designated state agency or entity) shall notify the appropriate law enforcement and occupational licensing, certification, or regulatory agency or entity, and provide Prescription Monitoring Information required for an investigation.

(c) The Board of Pharmacy (or designated state agency or entity) may provide Prescription Monitoring Information for public research, policy or education purposes, to the extent all information has been De-identified.

(d) The following persons, after successful completion of the educational courses identified in Section 9(a), may access the Prescription Monitoring Information in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar Protected Health Information under federal and state law and regulation.

(1) (insert Prescribers)

(2) (insert Dispensers)

(3) (insert all appropriate law enforcement personnel)

(4) (insert all appropriate occupational licensing, certification, and regulatory personnel)

(5) (insert all appropriate judicial authorities)

(6) (insert all appropriate personnel of the designated state agency or vendor/contractor establishing and maintaining the prescription monitoring program)

(e) The Board of Pharmacy (or designated state agency or entity) shall be immune from civil liability arising from inaccuracy of any of the information submitted to the Board of Pharmacy (or designated state agency or entity) pursuant to this Act.

Section 9. Education and Treatment.

(a) The Board of Pharmacy (or designated state agency or entity) shall, in consultation with the Advisory Board, implement the following education courses:

(1) An orientation course during the implementation phase of the PMP.

(2) A course for persons who are authorized to access the Prescription Monitoring Information but who did not participate in the orientation course.

(3) A course for persons who are authorized to access the Prescription Monitoring Information but who have violated laws or breached occupational standards involving Dispensing, prescribing and use of substances monitored by the PMP.

(4) A continuing education course for health care professionals developed by the American Society of Addiction Medicine and the state medical society on prescribing practices, pharmacology and identification, treatment, and referral of patients addicted to or abusing substances monitored by the PMP.

When appropriate, the Board of Pharmacy (or designated state agency or entity), in consultation with the Advisory Board, shall develop the content of the education courses described in paragraphs (1) – (3).

(b) The Board of Pharmacy (or designated state agency or entity), in consultation with the Advisory Board, shall strongly recommend the application of a course to inform the public about use, diversion and abuse of, and addiction to substances monitored by the PMP.

(c) The Board of Pharmacy (or designated state agency or entity), in consultation with the Advisory Board, shall, when appropriate:

(1) work with associations for impaired professionals to ensure intervention, treatment, and outgoing monitoring and follow-up; and

(2) ensure that individual patients who are identified and who have become addicted to substances monitored by the PMP receive addiction treatment.

Section 10. Unlawful Acts And Penalties.

(a) A Dispenser who knowingly fails to submit Prescription Monitoring Information to the Board of Pharmacy (or designated state agency or entity) as required by this Act shall be subject to (insert appropriate administrative, civil, or criminal penalty).

(b) A person authorized to have Prescription Monitoring Information pursuant to this Act who knowingly discloses such information in violation of this Act shall be subject to (insert appropriate administrative, civil, or criminal penalty).

(c) A person authorized to have Prescription Monitoring Information pursuant to this Act who uses such information in a manner or for a purpose in violation of this Act shall be subject to (insert appropriate administrative, civil, or criminal penalty).

Section 11. Evaluation, Data Analysis, And Reporting.

(a) The Board of Pharmacy (or designated state agency) shall, in consultation with the Advisory Board, design and implement an evaluation component to identify cost benefits of the prescription monitoring program, and other information relevant to policy, research, and education involving substances monitored by the PMP.

(b) The Board of Pharmacy (or designated state agency) shall report to the (insert appropriate state decision makers, eg, legislature) on a periodic basis, no less than annually, about the cost-benefits and other information noted in paragraph (a).

Section 12. Rules And Regulations.

The Board of Pharmacy (or designated state agency) shall promulgate rules and regulations necessary to implement the provisions of this Act.

Section 13. Severability.

If any provision of this Act or application thereof to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of the Act which can be given effect without the invalid provisions or applications, and to this end the provisions of this Act are severable.

Section 14. Effective Date.

This Act shall be effective on (insert specific date or reference to normal state method of determination of the effective date).

Comments

Section 8. Comment.

Patients have several traditional means other than a prescription monitoring program to access their medical information. However, some states' existing laws will require that patients have access to their prescription information which is maintained by a monitoring program. Those states will, therefore, need to include patients as a category of individuals able to access the prescription monitoring information under this section.